

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO.,)
LTD.,)
)
 Plaintiff,) C.A. No. 21-1015-JLH
)
v.)
)
SAREPTA THERAPEUTICS,)
INC.,)
)
 Defendant.)

Monday, May 6, 2024
4:39 p.m.
Teleconference

844 King Street
Wilmington, Delaware

BEFORE: THE HONORABLE JENNIFER L. HALL
United States District Court Judge

APPEARANCES:

MORGAN LEWIS & BOCKIUS, LLP
BY: AMY M. DUDASH, ESQ.
BY: AMANDA S. WILLIAMSON, ESQ.
BY: WAN-SHON LO, ESQ.
BY: KRISTA VINK VENEGAS, ESQ.
BY: MICHAEL T. SIKORA, ESQ.
BY: DAVID SCHRAEDER, ESQ.
BY: ALISON PATITUCCI, ESQ.

Counsel for the Plaintiff

1 APPEARANCES CONTINUED:

2
3 MORRIS, NICHOLS, ARSHT & TUNNELL, LLP
4 BY: JACK BLUMENFELD, ESQ.
5 BY: MEGAN DELLINGER, ESQ.

6 -and-

7 LATHAM & WATKINS,
8 BY: MICHAEL A. MORIN, ESQ.
9 BY: ERNEST YACOB, ESQ.
10 BY: DAVID P. FRAZIER, ESQ.
11 BY: REBECCA RABENSTEIN, ESQ.

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18 BY: CHARLES LIPSEY, ESQ.

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16:39:38 21
16:39:38 22 COURT CLERK: All rise. The United States
16:39:40 23 District Court for the District of Delaware is now in
16:39:43 24 session. The honorable Jennifer L. Hall presiding.

16:39:47 25 THE COURT: Please be seated. All right. We're
16:39:53 26 here for a pretrial conference. This is Nippon versus
16:40:00 27 Sarepta. It's 21-1015.

16:40:04 28 Let's go ahead and put our appearances on the
16:40:08 29 record.

16:40:08 30 MS. DUDASH: Good afternoon, Your Honor. Amy

16:40:11 1 Dudash from Morgan Lewis on behalf of Nippon Shinyaku and NS
16:40:16 2 Pharma. And with me are my colleagues from Morgan Lewis,
16:40:19 3 Amanda Williamson, Shon Lo, Michael Sikora.

16:40:24 4 MR. SIKORA: Hello.

16:40:24 5 MS. DUDASH: David Schrader.

16:40:26 6 MR. SCHRADER: Good afternoon.

16:40:27 7 MS. DUDASH: Krista Venegas. And Alison
16:40:30 8 Patitucci.

16:40:32 9 THE COURT: Good afternoon.

16:40:34 10 MR. BLUMENFELD: Good afternoon, Your Honor,
16:40:36 11 Jack Blumenfeld from Morris Nichols for Sarepta and UWA. We
16:40:41 12 have a number of people here along with me at counsel table.
16:40:44 13 Michael Morin from Latham & Watkins.

14 MR. MORIN: Good afternoon, Your Honor.

16:40:50 15 MR. BLUMENFELD: Next to Mr. Morin, Charles
16:40:50 16 Lipsey and William Raich from Finnegan Henderson.

16:40:54 17 MR. RAICH: Good morning.

16:40:55 18 MR. BLUMENFELD: Behind them, David Frazier and
16:40:56 19 Rebecca Rabenstein from Latham & Watkins. In the first row,
16:41:03 20 Ernest Yacob and Michele Johnson from Latham & Watkins.

16:41:07 21 In the second row, Ryan O'Quinn from Finnegan
16:41:10 22 Henderson. And next to Mr. O'Quinn, Marc Evans and Jessica
16:41:14 23 Driscoll, who are in-house at Sarepta. And I think I'll
16:41:18 24 stop there.

16:41:19 25 THE COURT: Great. Thank you very much. Good

1 afternoon and welcome to everyone.

16:41:21 2 So I can tell you from our side, our team's on
16:41:23 3 its eighth hour in court proceedings today, so we're going
16:41:27 4 to get as far as we can get tonight. If we have to recess
16:41:31 5 and pick it back up on the phone later this week, we'll do
16:41:34 6 that.

16:41:35 7 Our court reporter has been working diligently
16:41:38 8 transcribing some very fast talkers for the last eight
16:41:42 9 hours, so we'll take it nice and slow tonight with the idea
16:41:45 10 that we can pick up whatever we don't finish.

16:41:49 11 All right. Okay. So I have a checklist of
16:42:09 12 things to go through.

16:42:13 13 Why don't we start, while everybody is here,
16:42:18 14 with the MILs, if that make sense, unless you all had a
16:42:23 15 different order you wanted to proceed in.

16:42:27 16 MS. DUDASH: That makes sense, Your Honor.

16:42:29 17 THE COURT: All right. So we have NS MIL No. 1,
16:42:36 18 which has to do with precluding Sarepta from presenting
16:42:40 19 post-priority date evidence in support of its 112 position.
16:42:48 20 Shall we hear argument on that?

16:42:51 21 MS. LO: Thank you, Your Honor. Shon Lo on
16:42:58 22 behalf of Nippon Shinyaku. I believe that our papers set it
16:43:01 23 out, but I think the law is clear and Sarepta does not
16:43:05 24 dispute that compliance with the written description and
16:43:09 25 enablement requirement is determined as of the priority

16:43:12 1 date.

16:43:12 2 And here, their expert, Dr. Dowdy, is relying
16:43:16 3 extensively on post-priority date evidence to validate,
16:43:19 4 confirm, reinforce the inventors' purported discovery. And
16:43:26 5 Nippon Shinyaku submits that that is improper, there's a
16:43:28 6 high risk of confusing the jury and misleading the jury into
16:43:32 7 thinking that that evidence is relevant to the determination
16:43:36 8 of 112 satisfactions --

16:43:40 9 THE COURT: Can you give me your best example of
16:43:42 10 where you think he violates that or would confuse the jury?

16:43:45 11 MS. LO: -- yes, Your Honor.

16:43:47 12 THE COURT: So I don't take them to dispute that
16:43:51 13 the legal standard is that you have to look at 112 as of the
16:43:54 14 priority date. Presumably, they're going to say that for
16:43:57 15 some reason, this evidence is evidence of what a POSA would
16:44:01 16 understand as of the priority date, right? Okay.

16:44:03 17 MS. LO: Actually --

16:44:07 18 THE COURT: Everybody agrees on that, right?

16:44:09 19 MS. LO: I'm sorry, can you --

16:44:10 20 THE COURT: Everybody agrees that the 112
16:44:12 21 inquiry is the priority date -- as of the priority date.

16:44:15 22 MS. LO: Yes.

16:44:17 23 THE COURT: Okay. All right. Where is your
16:44:19 24 best example where they're getting that wrong?

16:44:21 25 MS. LO: I believe it is in Exhibit 1 to our MIL

16:44:24 1 number -- I'm sorry, Exhibit 2 to our MIL No. 1, which is
16:44:30 2 Dr. Dowdy's rebuttal report, specifically paragraph 92 is an
16:44:36 3 example, where Dr. Dowdy states that "numerous researchers
16:44:41 4 independently and repeatedly confirmed that the claimed
16:44:45 5 structural features of the Wilton patents confirmed the
16:44:55 6 claimed function of exon 53 skipping." There's a table
16:44:55 7 appearing, Fig. 13, on page 67.

16:44:58 8 And all of this evidence is post-priority date.
16:45:05 9 And he is relying on it to confirm, validate this hot spot
16:45:12 10 that is supposedly disclosed in the specification of the
16:45:15 11 Wilton patent.

16:45:16 12 Dr. Dowdy also relies on post-priority date
16:45:19 13 evidence to validate the structure function correlation that
16:45:23 14 he claims to perceive in the specification. And he also
16:45:28 15 provides opinions that purport to show recognition of the
16:45:32 16 hot spot by Dr. Wilton and others, even though he has no
16:45:36 17 personal knowledge of what was going through Dr. Wilton's
16:45:39 18 mind or the minds of these other researchers.

16:45:44 19 And I can provide citations to paragraphs from
16:45:48 20 his report, if you'd like.

16:45:49 21 THE COURT: No. That's fine.

16:45:50 22 MS. LO: Okay.

16:45:51 23 THE COURT: Anything else you wanted to add
16:45:53 24 before I hear from the other side.

16:45:54 25 MS. LO: Yes, sorry. And there's also -- not --

16:45:58 1 it's somewhat a complicating factor. But as you know,
16:46:03 2 Sarepta is asserting that the NS patents are obvious. The
16:46:09 3 NS patents have a priority date of 2011. And so he is
16:46:11 4 discussing references between the 2005 filing date of the
16:46:15 5 Wilton patents and the 2011 filing date of the NS patents as
16:46:20 6 reportedly validating, confirming, recognizing the hot spot.
16:46:26 7 And we believe that he should not be allowed to characterize
16:46:30 8 that evidence in that way.

16:46:31 9 We're not seeking to preclude them from relying
16:46:34 10 on the prior art references, obviously, you know, for what
16:46:37 11 they actually disclose or what they actually state. But the
16:46:39 12 way that he discusses them, you know, if he says that, oh,
16:46:43 13 and look, you know, these references validate the hot spot
16:46:46 14 or, look, these researchers recognized from the Wilton
16:46:49 15 specification that there was a hot spot, we feel that that
16:46:53 16 would have an extremely high risk of confusing the jury to
16:46:56 17 think that these references, you know, can support a
16:47:00 18 disclosure of the Wilton patents.

16:47:04 19 THE COURT: Let me ask you this. Couldn't this
16:47:06 20 be handled with a jury instruction that said something to
16:47:09 21 the effect of, you've heard testimony about things that
16:47:14 22 happened after the priority date and you should consider
16:47:17 23 that only to the extent that it's evidence about what a
16:47:21 24 person of skill in the art would have known or recognized as
16:47:24 25 of the priority date.

16:47:25 1 And I could even go further. I could even say,
16:47:28 2 post-priority stuff can only be used to show -- to -- or as
16:47:35 3 evidence of or relevance to what a person would have known
16:47:38 4 as of the priority date for purposes of written description
16:47:42 5 and enablement.

16:47:43 6 Wouldn't that help the jury then to understand
16:47:45 7 what they could use the evidence for?

16:47:47 8 MS. LO: I think it would help the jury but I
16:47:50 9 think that the risk of confusion is really great. These
16:47:52 10 patents are in the same field of research, they both focus
16:47:56 11 on exon 53. And for a juror to kind of separate that out
16:48:01 12 into what, you know, a 2008 reference discloses.

16:48:03 13 And if Dr. Dowdy says, oh, this 2008 reference
16:48:08 14 discloses and confirms that it's the recognition of a hot
16:48:08 15 spot, I think that that's -- there's a high risk that the
16:48:11 16 jurors will just conflate that evidence as improper -- using
16:48:16 17 it improperly.

16:48:17 18 THE COURT: All right. Thank you very much.

16:48:28 19 MR. YACOB: Good afternoon, Your Honor. Ernest
16:48:32 20 Yacob on behalf of Sarepta.

16:48:35 21 The Federal Circuit has repeatedly specifically
16:48:39 22 held that post-priority evidence by a patentee is allowed.
16:48:43 23 That was NS's main argument throughout its briefing. It's
16:48:47 24 wrong.

16:48:47 25 The -- in *Amgen v. Hoechst*, the Federal Circuit

16:48:50 1 accepted numerous post-filing publications demonstrating the
16:48:54 2 extent of the enabling disclosure. That's 314 F.3d at 1336.

16:49:01 3 In *Amgen v. Sanofi*, that's NS's case that they
16:49:02 4 rely on primarily. The Court again -- or the Federal
16:49:07 5 Circuit again allowed such evidence.

16:49:09 6 Quote, "The jury did not hear relevant
16:49:11 7 post-priority date evidence regarding written description
16:49:14 8 and enablement. This evidence may show, for example, that
16:49:18 9 practicing the invention did not require undue
16:49:21 10 experimentation, or that the disclosed species are
16:49:25 11 representative of the claimed genus."

16:49:26 12 That's in the 872 F.3d at 1379.

16:49:31 13 Sarepta's brief includes other examples of
16:49:33 14 Federal Circuit cases holding exactly the same thing. We're
16:49:37 15 happy to go through those, if it's helpful to Your Honor.
16:49:40 16 But Sarepta's post-priority evidence is proper here. It's
16:49:43 17 consistent with the Federal Circuit precedent.

16:49:47 18 Sarepta's patent describes and then claims ASOs
16:49:51 19 that induce exon skipping. The claimed ASOs are
16:49:56 20 structurally defined and they are finite in number. There's
16:50:00 21 no dispute in this case that a person of ordinary skill in
16:50:02 22 the art in 2005 knew how to make those ASOs.

16:50:06 23 What Sarepta is relying on in terms of
16:50:09 24 post-priority evidence is a wealth of direct specific
16:50:14 25 evidence confirming the teachings of the patent. Every ASO

16:50:20 1 that has the structural features that are taught in the
16:50:24 2 patent induces exon skipping.

16:50:30 3 And unlike the few cases that NS does cite for
16:50:35 4 its position, Sarepta is not trying to rely on post-priority
16:50:41 5 evidence as support for new discoveries, new developments.
16:50:46 6 Sarepta is not arguing that the post-priority evidence is
16:50:50 7 proper to show new ASO sequences, new properties of the
16:50:55 8 claimed ASOs.

16:50:58 9 And, you know, to add a layer of, you know,
16:51:02 10 common sense and fair play to all of this, it's NS that
16:51:06 11 introduced the post-priority evidence in the first place
16:51:09 12 through its own testing. What NS is trying to advocate for,
16:51:14 13 and what we submit cannot be right, is this double standard
16:51:18 14 that allows NS to tell the jury half the story, to tell the
16:51:23 15 jury that we've identified a number of embodiments that
16:51:28 16 allegedly do not work. And while precluding Sarepta from
16:51:34 17 relying on any post-priority evidence to refute that
16:51:37 18 contention and show that -- exactly the opposite is true.

16:51:42 19 So for all those reasons, Sarepta submits that
16:51:45 20 the Court should deny NS's motion.

16:51:48 21 THE COURT: Do you have any issue with some kind
16:51:50 22 of an instruction to the extent they're worried about the
16:51:53 23 jury being confused, having an explicit instruction that
16:51:57 24 makes it very clear that they may have seen post-priority
16:51:59 25 date evidence and that that should only be used for the

16:52:02 1 purpose -- 112 purpose of evidencing what a person of skill
16:52:06 2 in the art would have understood as of the priority date?

16:52:10 3 MR. SIKORA: Yeah, I mean, we don't dispute,
16:52:12 4 again, that -- that the evidence we're relying on is for the
16:52:15 5 purpose of illuminating the state of the art as of the
16:52:19 6 priority date.

16:52:19 7 And we also submit that, you know, to the extent
16:52:21 8 NS has any issue with that, they also can cross-examine the
16:52:24 9 witnesses on that point.

16:52:25 10 THE COURT: Okay. Thank you very much. And so
16:52:29 11 my questions may have revealed that we haven't closely
16:52:33 12 parsed the proposed final jury instructions yet. Maybe we
16:52:37 13 would have seen if that was already in there, but we're
16:52:39 14 working as fast as we can. Thank you very much.

16:52:43 15 MR. YACOB: Thank you, Your Honor.

16:52:43 16 THE COURT: So on MIL No. 1, to the extent it
16:52:48 17 requests a blanket exclusion of post-priority date evidence,
16:52:52 18 that request will be denied. If NS wants some type of a
16:53:01 19 curative instruction at the time the evidence is brought
16:53:03 20 in -- I'm not necessarily thinking that's appropriate -- you
16:53:08 21 could propose that to the other side. Or if there's a more
16:53:13 22 specific final jury instruction NS wants to propose, that's
16:53:17 23 something the Court would consider.

16:53:18 24 But to the extent we're asking for a blanket
16:53:21 25 exclusion, that's going to get denied.

16:53:23 1 All right. Let's move on to MIL No. 2 from NS,
16:53:29 2 which has to do with -- I guess, there are four issues that
16:53:32 3 it has to do with.

16:53:37 4 MR. SIKORA: Yes, your Honor. This is Mike
16:53:39 5 Sikora on behalf of Nippon Shinyaku and NS Pharma.

16:53:42 6 So these are four discrete instances where NS
16:53:45 7 and MS Pharma diligently acquired into specific issues that
16:53:50 8 we expect to be frankly, core trial narratives for Sarepta
16:53:56 9 and were stonewalled in discovery.

16:53:58 10 So the first example is how Sarepta chose its
16:54:01 11 accused product beyond it's 53. Ordinarily, you hear
16:54:06 12 defendants describe how they invented their product and how
16:54:09 13 it's amazing when we inquired about the specific selection
16:54:12 14 of the sequence, many of the witnesses said they had no
16:54:16 15 information other than a single sentence read in a document.

16:54:19 16 And when the author of that document, who ran
16:54:21 17 the research project, we had to subpoena her and approach
16:54:27 18 her, you see in the deposition transcripts, Sarepta
16:54:30 19 repeatedly objected on privilege grounds and instructed her
16:54:32 20 not to answer.

16:54:33 21 So for that reason, we don't think, at least in
16:54:35 22 that one, there should be any possibility of Sarepta now
16:54:39 23 introducing a new narrative as to why it selected the
16:54:42 24 product that elaborates beyond that single sentence that was
16:54:46 25 provided in the document.

16:54:47 1 THE COURT: Okay. And my recollection on the
16:54:49 2 papers, at least in my notes, was that they've said they're
16:54:52 3 not going to put on evidence about why it was selected as a
16:54:55 4 final product.

16:54:57 5 MR. SIKORA: If that's their representation,
16:54:58 6 then we think the Court should hold them to that throughout
16:55:01 7 the trial.

16:55:01 8 THE COURT: All right. Thank you very much. Is
16:55:03 9 that the representation?

16:55:10 10 MR. O'QUINN: Ryan O'Quinn for Sarepta.

16:55:15 11 Your Honor, we don't intend obviously to dive
16:55:18 12 into privileged material. The privilege claim here was
16:55:21 13 fairly limited to a single issue. Thousands of pages were
16:55:27 14 produced on the sequence selection issue and five witnesses
16:55:28 15 were made available. So we're not going to present what we
16:55:32 16 withheld from them. We're not going to make a
16:55:36 17 sword-and-shield situation, but we think we should be able
16:55:38 18 to talk about the general development of the product.

16:55:42 19 THE COURT: So let's get to specifics, instead
16:55:45 20 of generalities.

16:55:46 21 Are you going to have somebody say, we selected
16:55:48 22 it as a final product because blank?

16:55:52 23 MR. O'QUINN: We intend to make a presentation
16:56:09 24 consistent with that non-privileged evidence, focusing on
16:56:12 25 that single sentence that counsel has provided. But we

16:56:16 1 don't believe a broad exclusion of evidence is warranted
16:56:19 2 based on this.

16:56:20 3 THE COURT: So just to make sure I understand
16:56:23 4 and I'm not trying to be difficult, I'm just trying to
16:56:28 5 understand.

16:56:28 6 The witness is going to say, we selected it as
16:56:31 7 our final product because we talked to our attorneys and
16:56:36 8 that's what we decided. They're not going to say, because
16:56:39 9 it was the best product because some other reason we haven't
16:56:43 10 heard yet?

16:56:44 11 MR. O'QUINN: That's correct, Your Honor.

16:56:45 12 THE COURT: Counsel?

16:56:47 13 MR. SIKORA: If that's the only statement
16:56:49 14 they're going to elicit, that's fine with us.

16:56:52 15 THE COURT: All right.

16:56:52 16 Are we good?

16:56:54 17 MR. O'QUINN: Yes.

16:56:55 18 THE COURT: Okay. Thank you. Let's move on to
16:56:57 19 part 2B.

16:57:01 20 MR. SIKORA: So this is, it relates to other
16:57:06 21 exon 53 research that Sarepta conducted. Some of this is
16:57:09 22 actually the post-priority date evidence that Dr. Dowdy
16:57:11 23 talks about, was performed by Sarepta researchers, Pierce
16:57:23 24 Thosani and Ryszard Kole.

25 (Reporter clarification.)

16:57:27 1 MR. SIKORA: Pierce Thosani and Ryszard Kole.
16:57:27 2 And Nippon Shinyaku attempted to subpoena these witnesses.
16:57:30 3 Counsel for Sarepta then represented them in opposing those
16:57:36 4 subpoenas. Sarepta itself objected to the subpoenas and
16:57:38 5 they were successful in blocking that discovery.

16:57:41 6 In addition, when Nippon Shinyaku inquired with
16:57:44 7 Sarepta's witnesses that they did make available, including
16:57:48 8 the corporate witness, Dr. Schnell, he disclaimed
16:57:52 9 acknowledge of the design intent behind.

16:57:55 10 And so this is another where, you know, a patent
16:57:57 11 document says what it says, but elaboration beyond that of
16:58:01 12 saying, they were motivated to do this experiment based on
16:58:05 13 Dr. Wilton's work in 2005 or anything else as to why they
16:58:09 14 chose sequences, why they designed all of those to have the
16:58:12 15 length that they did, the complementary that they did, those
16:58:17 16 types of things that -- no Sarepta witness should be
16:58:20 17 speaking to those since we were denied discovery into that
16:58:23 18 and moreover, that should go equally to Sarepta's experts.
16:58:27 19 They shouldn't be speculating on circumstances that there is
16:58:29 20 no evidence in the record regarding --

16:58:31 21 THE COURT: Okay. So I just want to make sure I
16:58:34 22 understand. Dr. Kole and Thosani are not coming to trial,
16:58:40 23 right?

16:58:42 24 MR. SIKORA: That's our understanding, they are
16:58:43 25 not on either parties' witness list and they're outside --

16:58:45 1 THE COURT: So you're worried about one of their
16:58:48 2 witnesses saying, here's why they did what they did?

16:58:51 3 MR. SIKORA: Correct. And the way Dr. Dowdy
16:58:53 4 characterizes it in his report is one of those instances
16:58:56 5 when he describes it -- you know, you heard my colleague
16:59:00 6 describe confirming the 2005 University of Australia work
16:59:05 7 and things like that. There's nothing in the patent that
16:59:07 8 says that they were motivated, for example, by that. And
16:59:10 9 that's just one hypothetical example of something he might
16:59:13 10 say.

16:59:13 11 But if he wants to say, I looked at this
16:59:16 12 reference and this is what the reference says, that's one
16:59:18 13 thing. But trying to infer some other design intent that we
16:59:23 14 were precluding from discovering, shouldn't allowed.

16:59:26 15 THE COURT: Well, Dr. Dowdy doesn't say I talked
16:59:28 16 to these -- Drs. Kole and Thosani, does he?

16:59:33 17 MR. SIKORA: No, he doesn't.

16:59:35 18 THE COURT: Okay.

16:59:35 19 MR. SIKORA: But if he is attributing design
16:59:37 20 intent to what they're doing, rather than factually
16:59:40 21 representing what they did.

16:59:41 22 THE COURT: Okay.

16:59:42 23 MR. SIKORA: That's the line.

16:59:43 24 THE COURT: You don't think he should be able to
16:59:47 25 offer his opinion on what the design intent was based on the

16:59:51 1 records that he looked at and that you have --

16:59:55 2 MR. SIKORA: I don't think he should be able to
16:59:57 3 attempt to speculate as to what was actually in Thosani
17:00:01 4 and -- Dr. Thosani and Kole's mind when they were doing
17:00:04 5 that. I think that's a quintessential limitation on
17:00:08 6 experts, that they shouldn't be allowed to opine on others
17:00:11 7 intents.

17:00:12 8 So if he wants to describe the structure of the
17:00:14 9 research from that objective point of view, that's a
17:00:17 10 different question. I'm referring to why they might have
17:00:20 11 selected ASOs and what they were trying to do with their
17:00:24 12 experimentation.

17:00:25 13 THE COURT: And can you show me -- it's been a
17:00:28 14 long day. Can you show me an example of where he does that
17:00:32 15 in his report?

17:00:32 16 MR. SIKORA: I think the example would be the
17:00:34 17 table that my counsel referred you to. I think it was table
17:00:37 18 13, you mentioned. But it's the characterization of the
17:00:40 19 results. There's a -- accompanying paragraphs that describe
17:00:46 20 the research by Thosani and Kole as confirming the prior
17:00:51 21 research.

17:00:52 22 For example, there's no evidence that what they
17:00:54 23 set out to do in 2008/2009, when they did that
17:01:00 24 experimentation, was reconfirm prior research, for example,
17:01:01 25 right?

17:01:01 1 THE COURT: All right. Thanks very much. I
17:01:03 2 think I understand your position.

17:01:06 3 MR. O'QUINN: Your Honor, we don't intend to put
17:01:10 4 words in the mouth of witnesses that are absent. And we do
17:01:13 5 believe, however, that expert witnesses should be able to
17:01:16 6 interpret what they read from the perspective of a person of
17:01:19 7 ordinary skill in the art, which is all that we seek to do.

17:01:22 8 THE COURT: All right. Yeah. I understand now
17:01:25 9 better having heard from both sides.

17:01:27 10 So this -- this request is also going to be
17:01:32 11 denied without prejudice to re-raise if, for whatever
17:01:35 12 reason, Dr. Dowdy decides to opine on someone's intent.

17:01:48 13 2C?

17:01:49 14 MR. SIKORA: Yes, Your Honor. So this one
17:01:51 15 relates to licensing activity that Sarepta and/or the
17:01:54 16 University of Western Australia engaged in. Many of these
17:01:57 17 agreements were older agreements, focused in, for example,
17:02:00 18 2008, 2013, those sorts of time frames. And there are some
17:02:04 19 instances where witnesses were able to provide testimony
17:02:08 20 about the literal, you know -- you know, what provisions are
17:02:12 21 in the agreement, what scenario is the agreement, you know,
17:02:16 22 prepared for that you can read directly from the agreement.
17:02:19 23 That's fine.

17:02:20 24 What we don't want to see at trial is, for
17:02:22 25 example, a narrative saying, oops, Sarepta approached

17:02:26 1 Dr. Wilton at UWA in 2008 because they recognized his
17:02:29 2 amazing research. When, if that's the case, that testimony
17:02:32 3 was not given. And even though we probed it with both the
17:02:36 4 University of Western Australia and Sarepta's corporate
17:02:39 5 representatives.

17:02:39 6 THE COURT: So just to make sure I understand:
17:02:41 7 You don't want there to be a new story at trial about the
17:02:44 8 background for all these licenses that you haven't heard?

17:02:47 9 MR. SIKORA: Yes, Your Honor.

17:02:48 10 THE COURT: Okay. Thank you.

17:02:50 11 Are we going to hear a new story at trial about
17:02:53 12 the licensing negotiations that they haven't heard?

17:02:55 13 MR. O'QUINN: That is not the plan, Your Honor.

17:02:57 14 THE COURT: Okay.

17:02:59 15 MR. O'QUINN: We're a little worried about the
17:03:01 16 broad scope of what knowledge of negotiations means, that
17:03:03 17 was not part of any discovery that was sought. So we're
17:03:06 18 worried that that could be used to create constant sidebar
17:03:10 19 distractions at trial.

17:03:10 20 You know, the terms of these agreements speak
17:03:13 21 for themselves. Again, the damages experts that will be
17:03:15 22 looking at these have experience in interpreting these terms
17:03:18 23 and we don't believe there should be any limitations on
17:03:22 24 that, but witnesses, obviously, won't be able to go beyond
17:03:25 25 what they said at their deposition in terms of newly

17:03:29 1 acquired knowledge.

17:03:29 2 THE COURT: So this is, again, is going to be
17:03:31 3 denied without prejudice to re-raise if we hear testimony
17:03:34 4 that goes beyond what they said they knew about at their
17:03:41 5 depositions.

17:03:42 6 All right. Damages?

17:03:44 7 MR. SIKORA: Yes, Your Honor. So this relates
17:03:46 8 to a similar issue but for products that experts have --
17:03:50 9 Sarepta's expert have hinted at as being competing products
17:03:54 10 but has been appreciably quantified at least as to this,
17:03:58 11 Elevidys product, which is gene therapy that Sarepta
17:04:02 12 launched with a limited label for restricted age range in
17:04:06 13 June of this year.

17:04:07 14 And so one of the things that was specifically
17:04:11 15 inquired with Sarepta's corporate designee, was how Sarepta
17:04:16 16 had expectations for how follow-on products might effect
17:04:19 17 sales of the accused exon 53 products. And so for one of
17:04:24 18 those products that you don't see in our motion, which was a
17:04:28 19 PPMO 53 product, Sarepta's corporate designee was able to
17:04:33 20 provide a quantitative amount just saying hey, at this point
17:04:36 21 in time, we expected that sales would drop by X percent.

17:04:41 22 Sarepta did not provide that for Elevidys. Even
17:04:45 23 though there were references in the documents to this gene
17:04:48 24 therapy. We diligently inquired with the first corporate
17:04:52 25 representee about what Sarepta's expectations were at the

17:04:55 1 time and how it might effect sales after the product was
17:04:58 2 approved.

17:04:59 3 We, again, inquired with the corporate designee
17:05:01 4 who said that Sarepta did not know. Expert reports came,
17:05:07 5 their expert cited Elevidys as a potential factor but again,
17:05:12 6 did not actually assert that there was some sort of reduce
17:05:15 7 in demand that was going to be captured by this.

17:05:18 8 So if Sarepta created some sort of expectation,
17:05:20 9 it's not in their expert reports, it's not something that
17:05:23 10 was disclosed during fact discovery, and we don't think that
17:05:26 11 they should be allowed to do that as to these other two
17:05:29 12 products that weren't quantified and we didn't get those
17:05:32 13 quantitative financials or anything else to be able to
17:05:36 14 confirm sales data and other things like that.

17:05:38 15 THE COURT: So you don't want a new number at
17:05:40 16 trial, right, but you also don't want them to be able to say
17:05:44 17 generally what they expect the effect would be or that's
17:05:48 18 okay with you?

17:05:49 19 MR. SIKORA: For those products that it wasn't
17:05:51 20 disclosed on, that's correct. So for the one product I
17:05:54 21 mentioned that they did provide that number for PPMO 50, 53.
17:05:58 22 Of course, that's in the record. They disclosed that. We
17:06:01 23 don't have a dispute about that. It's for these other two
17:06:05 24 products for which we did seek information on the products,
17:06:07 25 didn't receive it during fact discovery. Their experts

17:06:10 1 haven't substantively done that. We don't want to see a new
17:06:15 2 narrative at trial that we can't rebut where they all of a
17:06:18 3 sudden say, oh, yeah, we've been launching this product for
17:06:21 4 eight months now and it's been doing great. So yeah, our
17:06:24 5 expectations is that these 53 products are going to go away
17:06:28 6 like that.

17:06:28 7 We don't want to see that type of new narrative
17:06:30 8 from either a fact witness or any of the experts. We'd
17:06:33 9 object based on the scope of their reports, but absolutely,
17:06:36 10 we don't want to hear it from fact witnesses either.

17:06:38 11 THE COURT: All right. Thank you very much.

17:06:43 12 MR. O'QUINN: Your Honor?

17:06:43 13 THE COURT: Do you understand what he's talking
17:06:44 14 about and are you going to do what he's worried about?

17:06:47 15 MR. O'QUINN: I can try to provide a little more
17:06:49 16 context.

17:06:50 17 So Elevidys is a gene therapy product as
17:06:53 18 Mr. Sikora represented, that was approved for a narrow
17:06:56 19 patient population about a year ago. Sarepta has given the
17:07:03 20 best landscape analysis that it has on this issue as of the
17:07:08 21 cutoff time of discovery.

17:07:09 22 This product is still in flux we are still
17:07:12 23 expecting an FDA decision on a potentially expanded patient
17:07:15 24 population in the coming weeks. The reason the witnesses
17:07:18 25 can't give a specific number is because there's no way to

17:07:21 1 know a specific number.

17:07:22 2 But we are worried about the risk, as you raised
17:07:24 3 a moment ago, that general holistic statements about these
17:07:29 4 other products, either at trial, potentially in post-trial
17:07:34 5 briefing are going to be scraped off because of an inability
17:07:37 6 to make a specific number.

17:07:41 7 And -- go ahead.

17:07:42 8 THE COURT: Can you just put a little more
17:07:44 9 detail on it? Explain to me what -- it sounds to me like
17:07:48 10 your witness might say something and so give me an idea what
17:07:52 11 the witness might say.

17:07:53 12 MR. O'QUINN: There isn't a future lost profits
17:07:55 13 claim in this case, so it's not a concern about speculation
17:07:58 14 by the experts as to where the sales will go in the coming
17:08:02 15 years.

17:08:02 16 We don't plan to make a lot about Elevidys in
17:08:06 17 this case. This case is about Vyondys, our product, and
17:08:11 18 Viltepso, their product. Exondys, the other product that
17:08:14 19 Mr. Sikora mentioned, has a small overlap but isn't a huge
17:08:19 20 factor in this damages case either. So we're just worried
17:08:23 21 that they're again trying to look for an overbroad exclusion
17:08:28 22 on the ground -- we're not planning to come up with a number
17:08:31 23 and say sales will be cannibalized by X%. We can't make
17:08:36 24 that statement.

17:08:36 25 THE COURT: But your witness will say Elevidys

17:08:41 1 is going to affect the sales, we think it's going to affect
17:08:45 2 the sales of the other products?

17:08:46 3 MR. O'QUINN: It's potentially also that the
17:08:49 4 physician witnesses on either side may discuss how that
17:08:52 5 product is affecting prescribing habits. And so that's the
17:08:56 6 fear, is that if we have a broad exclusion of any discussion
17:09:00 7 of Elevidys, you may not get the full picture for the jury
17:09:03 8 of how these patients are being treated. But we're not
17:09:07 9 going to make a categorical statement with a new number at
17:09:10 10 trial that they haven't received.

17:09:12 11 THE COURT: Okay. So when you say the
17:09:13 12 physicians might discuss it, those are your expert witness
17:09:17 13 physicians?

17:09:17 14 MR. O'QUINN: Experts also.

17:09:18 15 THE COURT: And is there anything about Elevidys
17:09:20 16 in the expert reports?

17:09:23 17 MR. O'QUINN: Yes.

17:09:24 18 THE COURT: Okay. All right. And they're not
17:09:26 19 going to testify outside of what they say in the expert
17:09:29 20 reports?

17:09:30 21 MR. O'QUINN: No, Your Honor.

17:09:32 22 THE COURT: All right. Anything else you wanted
17:09:34 23 to add before I hear again from either side?

17:09:34 24 MR. SIKORA: Nothing further, Your Honor.

17:09:35 25 THE COURT: All right. So on that one, again it

17:09:37 1 is going to be denied without prejudice to re-raise in the
17:09:41 2 particular context of the testimony.

17:09:45 3 MR. SIKORA: Yes, Your Honor.

17:09:47 4 MR. O'QUINN: Thank you, Your Honor.

17:09:48 5 THE COURT: All right. So this one has to do
17:09:56 6 with mentioning the IPRs. And so I guess it might be
17:10:14 7 helpful for me to hear from Sarepta first about how you
17:10:22 8 intend to use evidence of the IPRs, and then we can talk
17:10:28 9 about whether or not we think that the prejudice outweighs
17:10:34 10 the probative value.

17:10:38 11 MR. RAICH: Bill Raich of Finnegan, for Sarepta.

17:10:42 12 So the principal use for the IPRs will be to
17:10:46 13 reflect Sarepta's state of mind in response to NS's
17:10:50 14 allegations of willful infringement. So NS put Sarepta's
17:10:55 15 state of mind in play with their allegation of willfulness.
17:10:59 16 Before this litigation, Sarepta filed seven IPR petitions
17:11:03 17 showing its belief that the NS patents are invalid.

17:11:06 18 Further, the PTO's favorable institutions of
17:11:10 19 those proceedings shows the reasonableness of that belief,
17:11:14 20 as the institution requires establishing a reasonable
17:11:17 21 likelihood that the claims are unpatentable.

17:11:21 22 So we think the weight of the authority supports
17:11:23 23 our position that IPR evidence should be considered for
17:11:27 24 willfulness. Now, the cases that NS is relying on are in a
17:11:32 25 posit. Many of them don't address willfulness, or, for

17:11:36 1 example, in the case of Sight Sciences, they involve a
17:11:40 2 denial of institution on discretionary grounds.

17:11:42 3 And I think there's a fundamental difference
17:11:45 4 between a denial of institution and a grant of institution.
17:11:48 5 There are lots of reasons why IPR petitions can be denied.
17:11:52 6 It could be because the examiner already considered the art
17:11:56 7 and it's just exercising their discretion not to go forward.
17:12:00 8 There could be co-pending litigation, so it's a waste of
17:12:03 9 resources. There could be time bars, there could be
17:12:07 10 formality problems.

17:12:08 11 So there's a wide variety of things. I mean, in
17:12:11 12 all of those instances, the board wouldn't have reached,
17:12:14 13 like, the underlying substance of the merits of the
17:12:17 14 decision.

17:12:17 15 But a grant is different. There's only one
17:12:20 16 reason why the IPR petitions are granted. That's because
17:12:23 17 there's a reasonable likelihood that the claims are
17:12:26 18 unpatentable, and this is highly probative of the
17:12:30 19 reasonableness of Sarepta's belief, which undermines NS's
17:12:34 20 allegations of willful infringement.

17:12:36 21 THE COURT: Can I just ask -- I just want to
17:12:38 22 make sure I understand the timeline. Sarepta files the IPRs
17:12:43 23 a couple weeks before this lawsuit begins; is that right?

17:12:51 24 MR. RAICH: Weeks to months before, I don't have
17:12:53 25 the exact, but certainly before the lawsuit began. I don't

17:12:55 1 know the exact time.

17:12:56 2 THE COURT: And then the institution decisions
17:12:58 3 happened after we're in this?

17:13:01 4 MR. RAICH: That is correct, Your Honor. Yes,
17:13:02 5 that is correct.

17:13:03 6 THE COURT: And let me ask you this, if I agree
17:13:06 7 with them that I don't think it's appropriate and would be
17:13:15 8 confusing and prejudicial to the jury that the evidence that
17:13:24 9 the PTAB instituted the IPR, means that the patents are
17:13:32 10 less -- more likely to be obvious -- I think you are
17:13:36 11 tracking what I'm saying.

17:13:38 12 MR. RAICH: I am, yes.

17:13:39 13 THE COURT: You say you still want that evidence
17:13:46 14 to show state of mind. By that, you mean you filed -- you
17:13:49 15 were so convinced as to the invalidity of these patents that
17:13:52 16 you filed the IPR before this litigation even started.

17:13:56 17 MR. RAICH: A good faith belief. Yes, that's
17:13:59 18 right, Your Honor.

17:14:00 19 THE COURT: And do you think that -- I'm not
17:14:02 20 going to be able to articulate this very well. But, what
17:14:07 21 you're going to say is, we couldn't be willful infringers
17:14:12 22 because we thought that the patents were invalid and would
17:14:15 23 get invalidated in the IPRs, except for that I guess the
17:14:19 24 Federal Circuit has already held you shouldn't have been
17:14:22 25 able to file the IPRs to begin with.

17:14:24 1 So you really could have only thought they were
17:14:27 2 invalid based on how it ends up in this litigation, and
17:14:31 3 isn't that the jury that's supposed to be deciding if
17:14:34 4 they're invalid. Do you understand what I'm asking? Isn't
17:14:37 5 it confusing for the jury for you to say we didn't have a --
17:14:42 6 we weren't willful because we thought the patents would be
17:14:45 7 invalid, so we filed the IPR, but you really couldn't have
17:14:48 8 thought that because you weren't supposed to be filing the
17:14:51 9 IPR.

17:14:51 10 Does that make sense?

17:14:53 11 MR. RAICH: I understand the point, Your Honor.
17:14:55 12 I think from our perspective, Sarepta was acting in good
17:15:00 13 faith. Sarepta filed the IPRs, the petitions are
17:15:04 14 reflections of the beliefs of Sarepta.

17:15:06 15 The fact that ultimately based on contractual
17:15:09 16 reasons, you know, there was a Federal Circuit decision
17:15:13 17 overriding the district court's decision findings, having a
17:15:18 18 different interpretation.

17:15:19 19 We just don't think that in any way is
17:15:21 20 meaningful with respect to Sarepta's belief, and in fact,
17:15:24 21 it's a good faith belief that the patents are invalid. We
17:15:27 22 think it's a separate issue.

17:15:29 23 THE COURT: Is there anything I should take from
17:15:31 24 the fact that the IPRs get filed so close in time to when
17:15:34 25 this litigation starts? So we've got opinions from, I

17:15:37 1 think, Judge Bryson and others that say, well, if you file
17:15:40 2 for the IPR after the litigation gets started, it's not
17:15:43 3 really all that probative of willfulness.

17:15:47 4 Here, we just have a couple weeks before. Isn't
17:15:50 5 -- is that more probative --

17:15:52 6 MR. RAICH: I think --

17:15:53 7 THE COURT: -- of nonwillfulness?

17:15:56 8 MR. RAICH: I think if a litigation is upon you
17:15:58 9 and then in response to that litigation, you file IPR
17:16:01 10 petitions, that's a very different situation than filing
17:16:05 11 IPRs before a complaint ever gets filed.

17:16:07 12 And here, keep in mind, it was Nippon Shinyaku
17:16:10 13 that initiated the litigation. And so Sarepta filed its IPR
17:16:15 14 petitions, and then in response to that, Nippon Shinyaku
17:16:19 15 brought suit. But Sarepta's good faith belief existed
17:16:23 16 before the litigation was filed, and I think the IPRs are
17:16:27 17 strong evidence of that.

17:16:28 18 THE COURT: Okay. Thank you very much.
17:16:31 19 Anything you wanted to add before we hear from the other
17:16:35 20 side?

17:16:35 21 MR. RAICH: Just really quickly. I mean, I
17:16:37 22 think this has come up in terms of -- there is relevance to
17:16:41 23 the IPRs that if Nippon Shinyaku argues that the PTO has
17:16:45 24 previously considered the references or references that are
17:16:49 25 cumulative to them, and is making that point, I think it's

17:16:54 1 only fair that Sarepta be permitted to tell the jury that
17:16:56 2 upon a second look the US PTO found that there was a
17:17:00 3 reasonable likelihood that the references would result in
17:17:03 4 finding the NS patents unpatentable.

17:17:05 5 So if they put this into play by relying on what
17:17:08 6 the PTO did and relying on it, I think it's fair to say,
17:17:12 7 well, the PTO actually determined there was a reasonable
17:17:15 8 likelihood that the patents were invalid. That's sort of a
17:17:18 9 second independent play, depending on their actions during
17:17:21 10 the case.

17:17:22 11 THE COURT: All right. Thank you very much.

17:17:24 12 MR. RAICH: Thank you, Your Honor.

17:17:28 13 MS. DUDASH: Your Honor, as you saw from the
17:17:32 14 papers, the Federal Circuit has cautioned against the
17:17:34 15 limited value of PTAB decisions for purposes of willfulness.
17:17:38 16 That's the *SSL Services* case which cites others, that say
17:17:42 17 that the Federal Circuit has warned of the limited value of
17:17:45 18 actions by the PTO to establish a good faith belief of
17:17:48 19 invalidity.

17:17:49 20 This comes up in every case where a party wants
17:17:52 21 to use IPRs for willfulness. Numerous courts, as you
17:17:56 22 mentioned, Judge Bryson, in the *Iogen* case, and numerous
17:18:00 23 other ones cited in our paper, such as Judge Stark's cases,
17:18:03 24 *Integra Life Sciences* court, but I won't go through them
17:18:06 25 all, that have held that it simply is too prejudicial.

17:18:09 1 Even in the cases Sarepta cited, courts said you
17:18:13 2 couldn't say PTAB and IPR because the jury doesn't know what
17:18:16 3 that means. And then it will turn into a sideshow where
17:18:19 4 we'll have to explain that the patent office applies the
17:18:22 5 completely different presumption that invites confusion.
17:18:25 6 That's just simply unnecessary here.

17:18:28 7 One thing we do want to note is we just heard
17:18:32 8 argument just about willfulness. Dr. Dowdy, in his report,
17:18:35 9 as the court is familiar from the Daubert motion, cites this
17:18:39 10 all over the place to say the IPRs confirm his belief of
17:18:42 11 invalidity. That's exactly why there's prejudice here.

17:18:45 12 The jury is going to be confused and think that
17:18:47 13 invalidity must mean a reasonable likelihood, but we all
17:18:51 14 know it's clear and convincing evidence, and that's exactly
17:18:54 15 what the courts have found in excluding this.

17:18:56 16 We would say that we heard a lot about, you
17:19:00 17 know, Sarepta needs this to say that they challenged the
17:19:03 18 patents. If the Court is inclined, we would be willing to
17:19:07 19 say Sarepta could have a statement saying that they
17:19:10 20 challenged the validity of the patents before suit and end
17:19:14 21 it there. No mention of IPR, PTAB, institution decision,
17:19:19 22 which as the Court knows, NS wasn't able to respond.
17:19:22 23 There's no fulsome record.

17:19:23 24 There's a lot of courts that have excluded this
17:19:25 25 kind of evidence simply because the PTAB proceedings were

17:19:29 1 not complete. They had to withdraw them because they were
17:19:31 2 inappropriately filed, which is not an issue we're here to
17:19:35 3 relitigate. The federal circuit already found in our favor
17:19:37 4 on that.

17:19:38 5 But the bottom line is, we don't want this to
17:19:40 6 turn into a sideshow at trial and prejudice us in a way that
17:19:43 7 we think would constitute reversible error.

17:19:46 8 THE COURT: Let me ask you about that last
17:19:48 9 suggestion because that was sort of what I was thinking that
17:19:54 10 maybe the parties could work out. It sounds to me like you
17:19:58 11 might be amenable to it, where they could, say, put on
17:20:02 12 evidence that, yeah, we tried to challenge the patents by a
17:20:06 13 process to go to the PTO and the court later held that that,
17:20:12 14 the obviousness of the patent had to get decided by this
17:20:17 15 court, by this jury, or something like that.

17:20:19 16 MS. DUDASH: I think, Your Honor, we could work
17:20:21 17 something out. Just a statement, when you said put on
17:20:24 18 evidence, I have concerns with making it a sideshow. We
17:20:28 19 could probably work out the contours.

17:20:29 20 But as long as it wasn't going to be explaining
17:20:32 21 the patent office has this procedure, it's called an IPR,
17:20:36 22 here, let me tell you all about it. Because honestly, in
17:20:38 23 the time we're allowed. That's just not going to be
17:20:40 24 possible. And I think, in fairness, that simply is far too
17:20:43 25 confusing for the jury.

17:20:44 1 THE COURT: I understand what you are saying. I
17:20:46 2 will say this. If you're saying that they willfully
17:20:48 3 infringed, they ought to be able to have somebody sit here
17:20:52 4 on the stand and say no, we weren't willfully infringing and
17:20:55 5 we tried to challenge the patents three weeks before and,
17:20:58 6 you know, the Court said we couldn't do it that way, we had
17:21:01 7 to do it here.

17:21:02 8 So you're not precluding that a witness could
17:21:05 9 put on evidence but you just don't want it to go too far.

17:21:08 10 MS. DUDASH: Right, Your Honor. If it was a
17:21:09 11 statement like what you just said, we filed -- we attempted
17:21:13 12 to challenge the patent and it was decided that the jury
17:21:16 13 must decide and here is the reason I, as an expert, think
17:21:19 14 the patent is obvious, which of course will come in, we're
17:21:23 15 comfortable with that with the clear guardrails on. This is
17:21:29 16 not one of those opening-the-door situations.

17 (Reporter clarification.)

17:21:32 18 MS. DUDASH: Sorry.

17:21:33 19 And this is a -- I'm very concerned with
17:21:35 20 prejudice, so this is one area where I know on some of the
17:21:38 21 MILs we've been, you know, we could renew. The minute the
17:21:40 22 jury hears, the prejudice is really incurable.

17:21:44 23 So as long as we had clear guardrails, we are
17:21:46 24 amenable to that. And just a statement that they challenge
17:21:49 25 the patents, not really discussing the patent office.

17:21:52 1 That's exactly what other courts have found. Even when they
17:21:55 2 let this evidence in in different context, needs to be
17:21:59 3 excluded.

17:21:59 4 THE COURT: Understood. Thank you very much.
17:22:01 5 So on this one, I don't like IPRs getting discussed in front
17:22:10 6 of the jury because I agree with the courts that have held
17:22:13 7 that it's confusing and prejudicial, especially in light of
17:22:19 8 the different burdens and additionally, in light of the fact
17:22:23 9 that this is an institution decision and not a final
17:22:27 10 decision.

17:22:28 11 Also problematic here in light of the fact that
17:22:32 12 we've got this contractual provision that the Federal
17:22:37 13 Circuit has said means that Sarepta wasn't allowed to file
17:22:41 14 an IPR, although, again, my decision on this MIL is
17:22:45 15 independent of that.

17:22:48 16 We're not going to allow Sarepta to argue that
17:22:54 17 the PTAB's decision to institute supports Sarepta's view on
17:22:59 18 obviousness. That's not going to happen. I do think that
17:23:07 19 there is some minimal probative value potentially on having
17:23:12 20 Sarepta say that they weren't willful and they tried to
17:23:16 21 challenge these patents. And I'm hearing from NS that
17:23:19 22 they'll work with Sarepta on some guardrails to let that
17:23:23 23 evidence in.

17:23:25 24 So we're not going to have the PTAB's
17:23:28 25 institution decision come in. We're not going to have

17:23:32 1 anything the PTAB did be admitted in support of Sarepta's
17:23:39 2 obviousness opinion. We're going to have a minimal
17:23:43 3 discussion of Sarepta's decision to ask for an IPR as
17:23:52 4 evidence of their non-willfulness.

17:23:55 5 Does anybody have any questions about what I've
17:24:00 6 said?

17:24:02 7 MR. SIKORA: No, Your Honor.

17:24:05 8 THE COURT: All right. Thanks very much. All
17:24:06 9 right. And you should meet and confer to see if you can
10 come to agreement on making sense of the Court's ruling.

17:24:12 11 All right. We're turning to Sarepta's MIL and
17:24:15 12 we're going to start with Sarepta's No. 1, which has to do
17:24:24 13 with patents not in suit. And I'm not sure I 100%
17:24:28 14 understood everything that's going on here, so you might
17:24:30 15 have to walk me through it.

17:24:31 16 MR. RAICH: Yeah, Your Honor, Bill Raich again.
17:24:34 17 So our motion is to exclude evidence of satellite
17:24:39 18 proceedings related to patent other than the patents in
17:24:44 19 suit. And we think the case law overwhelmingly supports
17:24:47 20 exclusion because any possible probative value is outweighed
17:24:50 21 by jury confusion and sort of time wasted.

17:24:54 22 And so in terms of background, NS wants to rely
17:24:58 23 on certain types of information. And the first involve
17:25:03 24 prosecution histories of patent applications and patents
17:25:06 25 that are not related to the patents-in-suit. They are

17:25:10 1 different families, they have different priority dates, they
17:25:12 2 have different specifications, they have claims of different
17:25:15 3 scope. They're not prior art. They're later in time.

17:25:19 4 Many of the statements that they're seeking to
17:25:21 5 rely on relate to other exons, not Exon 53 or areas outside
17:25:27 6 of the Dr. Wilton's hot spot that you're going to hear a lot
17:25:30 7 about.

17:25:30 8 And so we think it's just extremely prejudicial
17:25:34 9 to Sarepta and UWA to have statements taken out of context
17:25:39 10 that were made in really very different situations with
17:25:43 11 different applications, different priority dates, you know,
17:25:49 12 just different claims, et cetera.

17:25:52 13 And so, again, this is, we think, very
17:25:56 14 prejudicial to Sarepta and UWA.

17:25:58 15 And let me give you one example that I think
17:26:01 16 might be helpful. So Nippon Shinyaku argues that Sarepta,
17:26:05 17 in some of these cases, sought claims over the Papawell
17:26:10 18 reference, which is one of the references that we're
17:26:12 19 asserting against the Nippon Shinyaku patent. And they
17:26:17 20 point out that Sarepta made statements that they feel are in
17:26:22 21 conflict with the positions taken in this litigation.

17:26:25 22 THE COURT: What do you mean by Sarepta? Do you
17:26:27 23 mean your -- an expert declaration or do you mean
17:26:30 24 prosecution counsel?

17:26:31 25 MR. RAICH: I mean, prosecution counsel in

17:26:33 1 pursuing -- yeah, good question. Prosecution counsel in
17:26:36 2 pursuing applications in these other families made
17:26:39 3 statements that they would like to use in this case, even
17:26:42 4 though they're very out of context.

17:26:44 5 And they're also ignoring the bigger picture,
17:26:47 6 which is that, although certain arguments were made, the
17:26:50 7 patent office actually rejected Sarepta's arguments. They
17:26:53 8 maintained the obviousness rejections. And Sarepta
17:26:58 9 abandoned those cases. So that information should be
17:27:00 10 excluded. It's really prejudicial and just not relevant to
17:27:05 11 our patent and our case here.

17:27:07 12 And I heard NS's counsel talk about, you know,
17:27:10 13 the time allotted in order to explain things. I think the
17:27:13 14 time allotted to address patents that are so different, that
17:27:19 15 have all of these different issues that would require an
17:27:22 16 incredible amount of context to explain what is going on is
17:27:25 17 a serious problem.

17:27:27 18 THE COURT: You're asking for more than just
17:27:29 19 them not using the statement of prosecution counsel, right,
17:27:31 20 you're also asking for them not to be able to use
17:27:34 21 declarations made by people who are going to be witnesses in
17:27:36 22 this trial?

17:27:37 23 MR. RAICH: I don't think it rises to that
17:27:46 24 level. I don't recall there being specific declarations,
17:27:49 25 but yeah, I am specifically discussing the prosecution files

17:27:56 1 and what happened in those proceedings. So -- I guess the
17:28:04 2 one -- the one, perhaps, exception to that -- and this goes
17:28:08 3 to the second category of evidence that is implicated by
17:28:10 4 this motion, and this relates to the interference, and so
17:28:15 5 it's a little bit different because the interference did
17:28:18 6 involve an application that was related to the Wilton
17:28:22 7 patents-in-suit.

17:28:23 8 But it's a very -- an interference is a
17:28:26 9 specialized proceeding at the US PTO that sort of is a
17:28:31 10 priority contest between that and a different earlier
17:28:35 11 application that was filed earlier and from a different
17:28:39 12 party. So it's a very different procedural posture.

17:28:43 13 And there were statements made by UWA, the
17:28:49 14 University of Western Australia, in the interference
17:28:51 15 proceeding that were made in support of the invalidity of
17:28:54 16 this unrelated patent application from a different entity
17:28:57 17 that's not a party to this suit and that had a different
17:29:00 18 priority date from the Wilton patents.

17:29:03 19 And so any minimal value -- any minimal
17:29:07 20 probative value, such as, you know, statements that they're
17:29:10 21 trying to take out of context is outweighed for the
17:29:12 22 potential for confusion.

17:29:14 23 Now, there's one further, I think, complicating
17:29:17 24 factor, and this actually goes to your question. And that
17:29:21 25 is, UWA's expert in that interference was someone named Matt

17:29:25 1 Wood. And Matt Wood is one of the NS experts in this case.

17:29:30 2 And there's just no reason to bring up his
17:29:34 3 declaration or statements that he made in that interference
17:29:37 4 talking about the different applications there, because he
17:29:41 5 has reports that he's submitted in this case about the
17:29:44 6 patents-in-suit. And we think that he should be limited to
17:29:48 7 offering testimony about the patents-in-suit, not what he
17:29:51 8 said in a different proceeding relating to different patents
17:29:54 9 in a different factual situation.

17:29:57 10 And we -- again, in terms of authority, we think
17:29:59 11 the authority is overwhelmingly in favor of excluding this
17:30:02 12 type of information.

17:30:04 13 And I will be brief, but just to discuss two
17:30:08 14 cases briefly, one is *Solvay v. Honeywell*. This is civ
17:30:15 15 number 06-557-SLR D.I. 329. And there, a motion in limine
17:30:22 16 sought to exclude statements made during the prosecution of
17:30:25 17 a related application -- a related application that
17:30:30 18 characterized the prior art after an examiner had made a
17:30:33 19 rejection. And the case was abandoned. And the Court
17:30:39 20 excluded that satellite proceeding because the marginal
17:30:45 21 relevance was far outweighed by the prejudice involved. We
17:30:48 22 think that that's the case here.

17:30:50 23 And then finally, the one case that they cited
17:30:52 24 in their opposition brief was a case called *Procter & Gamble*
17:30:56 25 *v. Nabisco*. And they cited it for the fact that prosecution

17:31:00 1 admissions are purportedly binding.

17:31:04 2 But there, the Court was discussing admissions
17:31:07 3 made during the prosecution of the patent that was
17:31:10 4 litigated. It was the same patent that was ultimately
17:31:13 5 litigated in the case, not these unrelated applications
17:31:16 6 with, you know, so many differences that would need to be
17:31:20 7 explained.

17:31:20 8 So I hope that's helpful. I'm happy to take
17:31:22 9 questions to try to put this more in context.

17:31:25 10 THE COURT: So I think what would be helpful is
17:31:27 11 so how do you expect this to come in, through the testimony
17:31:30 12 of their experts?

17:31:31 13 MR. RAICH: Yeah, their experts have cited to
17:31:36 14 these prosecution statements and are attempting to try to
17:31:39 15 explain how they are relevant to, you know, the instant
17:31:43 16 cases. And we just think that -- again, that the prejudice
17:31:46 17 substantially outweighs any marginal relevance that might
17:31:49 18 come from the statement.

17:31:51 19 THE COURT: I apologize. Do I have something in
17:31:53 20 the paper about exactly what paragraphs of their expert
17:31:55 21 report you think are going over the line?

17:31:58 22 And the reason why I'm asking is because it
17:32:03 23 would be helpful to me to decide it, but also because they
17:32:06 24 say this is really a move by your side to get out them
17:32:13 25 asking witnesses about declarations that they've made.

17:32:18 1 MR. RAICH: I mean, again, I think this goes far
17:32:20 2 beyond the declarations. And if we don't have a specific
17:32:24 3 paragraph for you, we'll get it to you by the end of this
17:32:27 4 conference or soon thereafter, because it's something that's
17:32:31 5 done substantially in their expert reports.

17:32:34 6 THE COURT: All right. Thanks very much. Let's
17:32:36 7 hear from the other side.

17:32:41 8 MR. SIKORA: So, first of all, Your Honor, to
17:32:44 9 the extent that Sarepta does provide anything later, we'd
17:32:47 10 like a chance to consider those and respond to the extent
17:32:49 11 that they weren't in the briefing.

17:32:51 12 Now, we disagree with counsel's characterization
17:32:53 13 of what is being done here across the board. So I want to
17:32:59 14 start first with the interference proceeding that was
17:33:01 15 mentioned, and then I want to transition over to these other
17:33:04 16 prosecutions of the other Sarepta patents.

17:33:06 17 So the interference involved exon 53 skipping
17:33:12 18 oligonucleotides from another University of Western
17:33:15 19 Australia family member. It involved certain counsel from
17:33:18 20 Sarepta in this room who were arguing factually to the PTAB
17:33:23 21 that the state of exon 53 skipping was unpredictable in
17:33:29 22 2005, continued to be unpredictable all the way through the
17:33:33 23 filing of those briefs, which was in 2014, 2015.

17:33:38 24 Those are party admissions that the University
17:33:41 25 of Western Australia made and that Sarepta made because it

17:33:44 1 was in control of the prosecution history. They were
17:33:46 2 successful in convincing the PTAB to adopt those factual
17:33:49 3 assertions, and they won that proceeding.

17:33:52 4 Then, when the patent-in-suit was being
17:33:54 5 prosecuted, the '851 Patent, Sarepta amended the claims so
17:33:57 6 they were identical to what they ultimately issued as. They
17:34:02 7 were rejected as obvious. And then Sarepta's patent
17:34:06 8 attorney controlling prosecution made virtually identical
17:34:10 9 arguments to those that were made in the interference, cited
17:34:13 10 the same evidence, almost word for word, the citation.

17:34:19 11 And then at the end, made the exact same
17:34:23 12 assertion that it continued, that lack of recognition -- or
17:34:26 13 I'm sorry, a recognition with a lack of unpredictability
17:34:29 14 continued beyond 2005. And again, this is in the
17:34:31 15 prosecution of the asserted patent.

17:34:33 16 And then concluded by saying, by the way, the
17:34:37 17 Patent Trial and Appeal Board already considered this exact
17:34:41 18 issue in this interference. They found the art was
17:34:46 19 unpredictable, and you, patent examiner, should adopt the
17:34:50 20 exact same ruling.

17:34:52 21 The patent office agreed, found the arguments
17:34:55 22 persuasive, withdrew the obviousness rejection. And the
17:34:59 23 asserted patent, having the exact claims that are being
17:35:02 24 asserted against Nippon Shinyaku now, issued.

17:35:05 25 Sarepta now wants to sweep all of that under the

17:35:07 1 rug and say that Nippon Shinyaku cannot mention any of those
17:35:12 2 statements from the interference.

17:35:13 3 And when I say "statements from the
17:35:15 4 interference," I want to be very clear that the use of the
17:35:18 5 interference is for the factual assertions being made.
17:35:22 6 Unlike counsel who represented that they were going to use
17:35:24 7 the IPRs or, in their brief, they mentioned European
17:35:29 8 proceedings for the outcome of those proceedings, we don't
17:35:32 9 intend to argue to the jury that, well, the patent office --
17:35:36 10 the PTAB found this so you should too.

17:35:39 11 What we instead plan to do is highlight the
17:35:41 12 factual assertions being made by the party. Where Sarepta
17:35:45 13 says the art remains unpredictable through 2014, remained
17:35:50 14 unpredictable past 2005.

17:35:52 15 Those party admissions by the patentee before
17:35:55 16 the patent office about a fundamental issue that's central
17:35:58 17 to the 112 issues in this case. Those are the statements
18 that are being used from the interference.

17:36:01 19 And we don't believe that Sarepta has a credible
17:36:04 20 way to argue that they shouldn't come in because they put
17:36:07 21 them at issue in the asserted claim by relying upon them
17:36:10 22 during prosecution of the patent.

17:36:12 23 When we had the meet and confer over this issue,
17:36:14 24 I asked counsel whether or not the statements from the
17:36:17 25 prosecution history where the prosecuting attorney, of the

17:36:21 1 '851 Patent specifically explicitly relied upon the
17:36:24 2 interferences of predictability, whether they intended that
17:36:28 3 to be excluded as well, even though it was in the
17:36:30 4 prosecution history of the asserted patent. They said yes.
17:36:34 5 That's how far they want to go.

17:36:35 6 And I do think the distinction is important that
17:36:38 7 we are focusing on factual party admissions when it comes to
17:36:43 8 unpredictability, when we're talking about interference.
17:36:46 9 Those are fair game. They're not something that are going
17:36:50 10 to require Sarepta to explain the context of the proceeding
17:36:53 11 or anything else. The only thing they will have to explain
17:36:55 12 away is anybody who is in the same position where they make
17:36:58 13 a factual admission and then have to try to explain it away
17:37:01 14 later when it's directly contradictory to their litigation
17:37:05 15 position.

17:37:06 16 That's the only prejudice that they have, and
17:37:08 17 it's not unfair prejudice. That's just having an
17:37:11 18 inconsistent prior party admission.

17:37:13 19 Now, the other set that counsel mentioned, these
17:37:15 20 additional prosecutions, you've heard Bestwick mentioned,
17:37:19 21 you've heard Tonsani mentioned. These are post-priority
17:37:23 22 date research performed by Sarepta, that Sarepta filed
17:37:27 23 patents on, that Dr. Dowdy relies upon as post priority date
17:37:31 24 evidence. But then when Nippon Shinyaku's experts want to
17:37:34 25 rely upon those same applications and the actions Sarepta

17:37:38 1 took with those same applications, now that's out of bounds
17:37:41 2 because, again, Sarepta is making arguments that are
17:37:44 3 inconsistent with its litigation position.

17:37:47 4 So, if it's fair game for Dr. Dowdy to introduce
17:37:50 5 the subsequent research by Sarepta in their patent
17:37:53 6 applications, it should also be fair game for Nippon
17:37:57 7 Shinyaku to then flag to the jury what exactly Sarepta
17:38:00 8 asserted it had invented in those applications and what was
17:38:04 9 patentable over their asserted prior art.

17:38:06 10 And so with those, even though there is some
17:38:09 11 discussion of the specific claims being sought, there is
17:38:12 12 sponsoring expert testimony to put it in context. The jury
17:38:17 13 will be instructed. We've agreed to play the patent video
17:38:20 14 which talks about prosecution. So this is not a situation
17:38:22 15 for those where the jury is going to have to be instructed
17:38:25 16 about other proceedings that aren't already at issue.

17:38:29 17 And so we think that there's a stark difference
17:38:32 18 between the uses that Nippon Shinyaku is using this for and
17:38:35 19 what Sarepta is using this for. And realistically, if they
17:38:41 20 are allowed to use post-priority date evidence, that should
17:38:44 21 open the door to Nippon Shinyaku's reliance to rebut their
17:38:48 22 points, that they're making for invalidity and validity as
17:38:52 23 well.

17:38:53 24 So pause there if you have any questions for me,
17:38:55 25 because I know that was a lot of information.

17:38:57 1 THE COURT: No, I don't. Thank you very much.
17:38:59 2 So I think on this one, what we'd like to do, is take a
17:39:02 3 closer look at it. Not because we think that the issue is
17:39:08 4 particularly challenging to decide, but because we just want
17:39:13 5 to understand exactly what's being objected to.

17:39:16 6 So I'm going to ask Sarepta to let us know with
17:39:19 7 a letter by noon tomorrow which paragraphs exactly they're
17:39:24 8 talking about and we'll take a look at those. And if we
17:39:29 9 need briefing from the parties, we'll ask for it at that
17:39:35 10 point, but just a letter with the paragraphs and no argument
17:39:40 11 would be our preference.

17:39:43 12 And I was mostly tracking, but not 100%, so I
17:39:48 13 think we just need to take some time and I want to get you a
17:39:51 14 good decision.

17:39:54 15 MR. SIKORA: Yes, Your Honor.

17:39:56 16 THE COURT: All right.

17:39:58 17 MR. RAICH: May I briefly respond to a couple of
17:40:00 18 those points?

17:40:01 19 THE COURT: Sure.

17:40:02 20 MR. RAICH: Okay. Thank you.

17:40:09 21 Just a few things about this: First of all, in
17:40:14 22 Category 1, involving sort of the other prosecution cases
17:40:17 23 that are unrelated, you know, if the -- if the jury were to
17:40:23 24 hear arguments about the argument -- if the jury were to
17:40:29 25 hear arguments that were made in those cases by Sarepta in

17:40:32 1 an attempt to get those claims allowed, they would also need
17:40:35 2 to hear that the PTO rejected those arguments and that
17:40:38 3 Sarepta abandoned those cases. I think that's only fair, to
17:40:42 4 provide sort of the full context for what happened there.

17:40:44 5 We think it's much simpler to just preclude this
17:40:48 6 evidence rather than having to go through it but that is
17:40:51 7 certainly fair from our perspective.

17:40:53 8 Second of all, with respect to Dr. Wood, the
17:40:55 9 interference expert, you know he's now their expert and they
17:40:58 10 really shouldn't be given the opportunity to bolster his
17:41:02 11 opinions by saying that he used to be an expert for UWA.
17:41:06 12 That seems, to us, to be prejudicial.

17:41:11 13 A third point, again, this is -- this is very
17:41:16 14 much like the PTAB IPR decisions. They're talking about
17:41:22 15 different proceedings, with different specific issues, all
17:41:25 16 the things that I mentioned about priority dates, claim
17:41:28 17 scope, patent specifications, the types of proceedings, it
17:41:33 18 would take -- it is a very fast, compressed trial with
17:41:36 19 patents going in both directions and we think the time that
17:41:39 20 would be needed to explain all of that, simply would be
17:41:46 21 exceedingly problematic and prejudicial.

17:41:51 22 I think in terms of their statement about what's
17:41:57 23 in the file history, we would be, of course, fine with them
17:42:03 24 citing a specific statement in the 85 -- in the file history
17:42:05 25 of the Wilton patent that's at suit. That's not the issue.

17:42:09 1 But we don't think that that opens the door to all of the
17:42:13 2 briefing and declarations and underlying materials from the
17:42:16 3 interference.

17:42:18 4 So --

17:42:19 5 THE COURT: Thank you very much.

17:42:21 6 MR. SIKORA: Your Honor, if I may briefly, just
17:42:23 7 one or two points?

17:42:25 8 THE COURT: Sure.

17:42:27 9 MR. SIKORA: So first of all, I think it's
17:42:30 10 important to note, if you look at the face of the '851
17:42:33 11 Patent, the references that were provided to the Patent
17:42:36 12 Office during prosecution included the underlying briefing
17:42:39 13 from the PTAB and those were cited to the Patent Office. So
17:42:43 14 this isn't a situation where it's not intrinsic evidence to
17:42:49 15 the asserted patent in that patent's prosecution and in any
17:42:52 16 event, because it's a related family member, it's intrinsic
17:42:55 17 evidence even if Sarepta hadn't specifically cited it in
17:43:00 18 connection with the '851 Patent.

17:43:01 19 So we don't think that that distinction holds
17:43:04 20 water.

17:43:04 21 As to Professor Wood, if their representation is
17:43:08 22 that they are not going to impeach his credibility at all,
17:43:11 23 at trial, then maybe we can discuss the issue that they
17:43:16 24 brought about notifying that he previously worked for
17:43:18 25 Sarepta.

17:43:19 1 But if they do anything to impeach his
17:43:21 2 credibility, it's fair game to point out that he was willing
17:43:24 3 to offer virtually the exact same opinions about exon 53
17:43:28 4 skipping the unpredictable for Sarepta and UWA when they
17:43:33 5 wanted him to.

17:43:34 6 So with that, I'll stop.

17:43:35 7 THE COURT: All right. Thanks very much.

17:43:38 8 All right. We'll take that one under
17:43:42 9 advisement.

17:43:43 10 Let's move on to Sarepta Motion No. 2.

17:43:51 11 MR. MORIN: Good afternoon, Your Honor. Mike
17:43:54 12 Morin on behalf of Sarepta.

17:43:55 13 I think we've said most of what we wanted to say
17:43:57 14 in our papers but if you'd like a little bit more
17:44:01 15 background, both parties and both companies, when they got
17:44:06 16 their products approved, did separate and independent tests,
17:44:10 17 not head-to-head tests but separate tests, to determine the
17:44:15 18 amount of dystrophin increase that their respective products
17:44:19 19 got. They were not comparative, they were with different
17:44:22 20 patient population, they were different studies, different
17:44:25 21 attributes and for that reason, the FDA won't allow either
17:44:28 22 side to make any comparative claims about the efficacy of
17:44:31 23 the two products compared to each other.

17:44:33 24 Flat out-of-bounds and we cited in our brief,
17:44:35 25 their admissions by the 30(b)(6) witness on that, the

17:44:38 1 admissions by their expert on that, the documents that
17:44:42 2 support that. We --

17:44:44 3 THE COURT: And they're not going to do that.

17:44:47 4 MR. MORIN: They say they're not going to do
17:44:49 5 that but in our reply brief, you may have another -- this is
17:44:52 6 on page -- we have a one-page reply brief where we pointed
17:44:55 7 out on page 3, where they say they're not going to try to
17:44:57 8 say that one is better than the other.

17:44:58 9 But on page 2, they cite that they wanted to say
17:45:01 10 that they have the highest dystrophin in levels and if the
17:45:04 11 question is, I'm not allowed to compare myself to Jack,
17:45:07 12 Mr. Blumenfeld, but I'm going to say I'm the tallest of the
17:45:10 13 two of us, you're doing the exact same thing.

17:45:12 14 So they want to say that they have the highest
17:45:15 15 dystrophin levels as compared to us and they say that on
17:45:18 16 page 2 and their expert has said that in their report.

17:45:22 17 What we fear, Your Honor, we have no problem and
17:45:24 18 we'll do the same thing, we have competing patents, Your
17:45:27 19 Honor, so we're seeking lost profits. Your Honor is well
17:45:30 20 aware of lost profits. We have no problem with our friends
21 wanting to get up say they compete with one another, we have
17:45:36 22 safe and effective products and all of that.

17:45:38 23 But the turmoil and the prejudice to us if they
17:45:41 24 suggest in any way that their level of 5% should be compared
17:45:45 25 to our level of 1%, both of which are tenfold increases from

1 the baseline levels with different patient populations, if
2 there's even a suggestion that that shows in any way that
3 theirs is better than ours, which is disallowed by the FDA,
4 and which they say they're not going to do on page 3 but
5 they do on page 2 of their brief, then we have to unwind
6 that because as Your Honor must appreciate any jury is going
7 to look at it and any suggestion that their product is
8 better than ours is going to start affecting who they
9 believe or the innovators here and what's better than what.

10 When it is uncontested, I think, and the FDA has
11 mandated that those comparisons wouldn't mean anything, that
12 they're not the same studies, then they're not comparable
13 and no one is allowed to say it outside of the courtroom, I
14 don't know why they should be allowed to say it inside the
15 courtroom.

16 And we also set forth in -- if your Honor thinks
17 it wouldn't be an issue, I mean, on the possibility that
18 they might do this, that was triggered by some of what they
19 did in the litigation, their expert reports debating, these
20 are different studies and this one had this patient
21 population.

22 None of that should come in front of the jury.
23 They can certainly say they have a safe and effective
24 product. We won't dispute that actually. I think with both
25 sides, there's a two supplier market generally in these exon

17:46:57 1 skippers, that either side can say they're in direct
17:47:01 2 competition and we have lost profits claim, we're going to
 3 do the same thing. We can come up and try to prove there
17:47:05 4 are other metrics, ours is better than theirs. No one
17:47:06 5 should be doing that. Both are good, effective drugs,
17:47:08 6 that's all they need.

17:47:10 7 THE COURT: All right. Let's hear from the
17:47:12 8 other side.

17:47:13 9 MR. SIKORA: Just briefly, I just want to
17:47:20 10 reaffirm what your Honor noted, which is that we already
17:47:22 11 stated that we don't intend to draw clear comparisons. The
17:47:25 12 quote that they keep using in their brief, I think is taken
17:47:29 13 significantly out of context, what the expert was opining on
17:47:33 14 if you read that section is not A clinical comparison, it's
17:47:37 15 actually from an economic expert.

17:47:38 16 What the economic expert is rebutting is this
17:47:41 17 allegation that Nippon Shinyaku's ramp-up period in the
17:47:45 18 but-for world, how long it took them to get up to scale,
17:47:49 19 would have taken less time -- or I'm sorry, would have
17:47:52 20 taken -- Sarepta alleged that it would have taken more time
17:47:56 21 for Nippon Shinyaku to do what they did when they ramped up.
17:47:58 22 And the expert was rebutting that by pointing to factors in
17:48:02 23 the market that were not present for the Viltepso product
17:48:06 24 that were present for Vyondys 53.

17:48:11 25 So in Vyondys 53, Sarepta's product in the case,

17:48:12 1 there was a clinical hold -- or I'm sorry, not a clinical
17:48:15 2 hold but a complete response letter issued and the FDA
17:48:19 3 actually deferred judgment and did not approve it right
17:48:21 4 away.

17:48:21 5 So it's about a market perception problem that
17:48:24 6 Nippon Shinyaku did not have to face. That's the crux of
17:48:28 7 the opinion. That's the opinion that would be elicited at
17:48:31 8 trial. It's not -- the opinion never was focused or
17:48:35 9 attempting to prove superiority.

17:48:39 10 So I think if you read the full opinion in
17:48:42 11 context, the goal of the expert, you know, he's not the
17:48:44 12 clinician. If you look at the clinician's report, the
17:48:47 13 clinician doesn't make -- that quote wasn't taken out of the
17:48:50 14 doctor's report, that was taken out of the economics expert
17:48:52 15 report where he's talking about market perception and what
17:48:55 16 led to the ramp-up period.

17:48:57 17 So I think the opinion that he's going to give
17:48:59 18 at trial is not going to be the cherry-picked portion
17:49:02 19 Sarepta relies upon. I can firmly say we don't intend on
17:49:08 20 making explicit compare- -- you know, superiority. The data
17:49:09 21 is what the data is, but we don't intend to make specific
17:49:12 22 comparisons between them.

17:49:13 23 THE COURT: Okay.

17:49:14 24 Go ahead, Counsel.

17:49:15 25 MR. MORIN: Your Honor, I worry when he says

17:49:18 1 clear comparisons and explicit comparisons and he qualifies
17:49:20 2 that. First, my colleagues who are more familiar with the
17:49:23 3 clinical reports as to Dr. Strober, their clinician says
17:49:28 4 physicians could decide Viltepso better based on those
5 numbers.

17:49:32 6 So now if it's one separate move and they want
17:49:33 7 to say we're not saying it's better, we're just saying
17:49:36 8 people could conclude it's better, then you have to unwind
17:49:39 9 it in the exact same way. So maybe we don't have an issue.

17:49:42 10 THE COURT: It doesn't sound like we necessarily
17:49:44 11 do. Do you want to talk -- he's saying his expert's only
17:49:48 12 going to say what's in the report.

17:49:50 13 MR. MORIN: I understand, but maybe we can -- I
17:49:52 14 think if we're on the same page, then there should be no
17:49:55 15 problem with an agreement that no one is not only going to
17:49:57 16 say one is better than the other, but no one is going to
17:50:00 17 suggest that one is better than the other; putting the
17:50:02 18 numbers side by side or saying people might decide on this
17:50:07 19 because it's a higher number. If we're in agreement there,
17:50:09 20 we're fine.

17:50:10 21 THE COURT: Okay. Maybe this is something
17:50:11 22 you-all can work on. I don't want to preclude him from
17:50:15 23 talking about what's in their label either, right, and have
17:50:18 24 you say that they've broken the agreement. So maybe it just
17:50:20 25 has to do with putting them all right next to each other on

17:50:24 1 a split screen.

2 MR. MORIN: It's on a split screen, or this is
17:50:26 3 5, let's turn your label, it's 1; anything like that. Of
17:50:28 4 course, they can talk about what's on their label, but we
17:50:31 5 don't want any suggestion. The little bit of suggestion of
17:50:35 6 any length to a jury, Your Honor, that theirs is better
17:50:38 7 based on that number will take forever to unwind because
17:50:42 8 jurors are going to look at that and could conclude that one
17:50:44 9 is better than the other, which is something the FDA has
17:50:45 10 specifically said, and I think our friends agree, you can't
17:50:49 11 conclude from there. So we should stay away from that.

17:50:50 12 THE COURT: Understood. Is that something you
17:50:51 13 might be able to work with them on?

17:50:53 14 MR. SIKORA: Yes, Your Honor. I think this is a
17:50:55 15 situation similar to earlier ones where, you know, on a
17:50:57 16 case-by-case basis if something crosses the line, I think
17:51:01 17 should be raised with -- you know --

17:51:01 18 THE COURT: With the understanding, though, that
17:51:03 19 we're not going to have any direct comparisons at trial.

17:51:06 20 MR. SIKORA: Right. We do not intend to put
17:51:08 21 them on a slide side by side and say 5.9 is better than .9%.
17:51:17 22 We don't intend to provide that demonstrative.

17:51:20 23 THE COURT: Okay.

17:51:20 24 MR. MORIN: Okay. And hopefully we all agree
17:51:22 25 that it goes beyond providing that demonstrative and it's

17:51:22 1 not -- we just saw five, now let's talk about the other
17:51:25 2 product. This should be not mentioned in accordance with
17:51:29 3 one another.

17:51:30 4 MR. SIKORA: I think this is where it goes to,
17:51:33 5 Your Honor's point, that I'm hesitant to say more because I
17:51:36 6 don't want to preclude us from --

17:51:38 7 THE COURT: Right. I think -- all right. We're
17:51:39 8 going to hear something about -- we're going to hear
17:51:55 9 something from NS's damages expert about ramp-up time. And
17:52:00 10 none of that testimony should be discussing that our product
17:52:04 11 is better or anything like that. That's where we'll leave
17:52:08 12 it. And I think everybody understands how we're going to
17:52:13 13 proceed.

17:52:13 14 MR. MORIN: We do. And just, Your Honor, not to
17:52:15 15 beat a dead horse, and then I will sit down. The reason we
17:52:18 16 brought it as limine rather than Daubert is it could affect
17:52:22 17 anything. You opened and you say, let's look at this label,
17:52:24 18 now let's look at that label, and you start making
17:52:26 19 insinuations, which is why we didn't limit it to a Daubert.
17:52:28 20 It could be cross-examination, it could be all sorts of
17:52:31 21 things. That's why we brought it in this forum, Your Honor,
17:52:34 22 just so you're aware.

17:52:35 23 THE COURT: I understand. All right. So that's
17:52:38 24 resolved.

17:52:41 25 And so now we have Sarepta MIL No. 3.

17:53:03 1 MR. RAICH: Bill Raich again, Your Honor. So
17:53:05 2 I'm going to try to respond, because there was an order that
17:53:09 3 you issued relating to our MIL No. 3, where you indicated
17:53:14 4 that you're considering whether to clarify or amend the
17:53:18 5 construction of base sequence before the case goes to the
17:53:22 6 jury.

17:53:22 7 And I really want to answer your questions in
17:53:26 8 discussing this. Just by way of background, so Sarepta
17:53:30 9 proposed a construction of base sequence that required a
17:53:37 10 100% complementary throughout the entire length of the
17:53:40 11 antisense oligonucleotide. And then Nippon Shinyaku's
17:53:44 12 proposed construction did not. It required only that a
17:53:46 13 portion of the antisense oligonucleotide have a 100%
17:53:52 14 complementary, but there could be another portion that was
17:53:56 15 random basis, for example, under the way that they were
17:54:00 16 interpreting base sequence. And that construction was
17:54:01 17 adopted.

17:54:02 18 Now, we think that clarifying the construction
17:54:05 19 of base sequence to require a 100% complementary through the
17:54:10 20 full length of the antisense oligonucleotide would
17:54:15 21 streamline the written description and enablement issues in
17:54:18 22 dispute.

17:54:19 23 So let me try to explain this. So Dr. Hastings,
17:54:22 24 who is Nippon Shinyaku's expert, argues that the claims are
17:54:26 25 overly broad because they cover oligonucleotides that have

17:54:32 1 random bases or things that fold on themselves instead of
17:54:35 2 binding to the target. And those types of claim scope
17:54:41 3 arguments with a construction that makes it clear that the
17:54:45 4 claim is directed to things that are a 100% complementary
17:54:50 5 through the full length, would eliminate those types of
17:54:53 6 claim scope arguments that allow for the random basis or the
17:54:57 7 self-folding oligonucleotides.

17:55:00 8 Now, she has other arguments that she makes for
17:55:03 9 112 based on, for example, specification, you know, support
17:55:08 10 in the specification for specific claim terms. Those would
17:55:11 11 not be foreclosed by tightening the construction. And so in
17:55:15 12 that sense, NS and Dr. Hastings would be free to make
17:55:19 13 written description enablement arguments on that basis.

17:55:22 14 So we think that a narrowing construction is
17:55:25 15 appropriate and I'll explain why momentarily. But it would
17:55:36 16 be appropriate and it would prevent Dr. Hastings from
17:55:40 17 offering testimony about the scope of the genus to the jury.
17:55:46 18 And so I want to turn now to the construction issues and why
17:55:50 19 we think that the narrowing construction is appropriate.

17:55:54 20 So the construction that NS offered is -- we
17:55:58 21 think it's just wrong. And there are really -- it is wrong
17:56:03 22 on the law and it is wrong on the facts.

17:56:06 23 So in terms of the law, Claim 1 separately
17:56:12 24 requires a bay sequence comprising 12 consecutive bases of
17:56:18 25 seek ID number 195, okay. That's a requirement of the

17:56:22 1 claim. And that sequence, those 12 bases, are 100 percent
17:56:29 2 complementary to the exon 53 target region.

17:56:34 3 So if you say that the bay sequence limitation
17:56:40 4 applies to only part of the claim, only part of the claim
17:56:44 5 needs to be a hundred percent complementary -- excuse me,
17:56:48 6 only part of the oligonucleotide needs to be a hundred
17:56:52 7 percent complementary, there's already part of the claim
17:56:55 8 that requires that, and that's the seek ID number 195
17:56:59 9 limitation. It's already there.

17:57:00 10 So the term, a bay sequence comprising 12
17:57:05 11 consecutive bases of seek ID number 195 renders superfluous
17:57:10 12 the bay sequence that requires a hundred percent
17:57:15 13 complementary throughout the antisense oligonucleotide.
17:57:17 14 Now, scientifically -- oh, one other thing is that Dr.
17:57:21 15 Hastings, Nippon Shinyaku's expert, admits that under that
17:57:26 16 construction, the term is superfluous. She says in her
17:57:31 17 opening expert report at paragraph 45, "Because a bay
17:57:35 18 sequence comprising 12 consecutive bases of seek ID number
17:57:41 19 195 is a hundred percent complementary, the 12 consecutive
17:57:42 20 bases of the target region, as construed by the Court, I
17:57:46 21 interpret the limitation, a hundred percent complementary,
17:57:50 22 to be subsumed by the limitation at least 12 consecutive
17:57:54 23 bases of seek ID number 195."

17:57:57 24 The constructions that render claim terms
17:57:59 25 superfluous are disfavored. So we think that legally that's

17:58:03 1 inappropriate. And scientifically, there's just no
17:58:07 2 publication that describes an antisense oligonucleotide as
17:58:12 3 having two or more bay sequences. You're just talking about
17:58:16 4 the bay sequence of the antisense oligonucleotide.

17:58:20 5 Sarepta's construction, which requires a hundred
17:58:24 6 percent complementary, we think should be adopted. So the
17:58:28 7 specification depicts every antisense oligonucleotide with a
17:58:32 8 single sequence. The understanding of the person of
17:58:36 9 ordinary skill is that in the context of an antisense
17:58:40 10 oligonucleotide there's a correlation between the bay
17:58:42 11 sequence and what the antisense oligonucleotide is.

17:58:47 12 And Nippon Shinyaku's attacks, we think just
17:58:49 13 aren't with merit. Their principal attack on Sarepta's
17:58:53 14 proposed construction involves something called a WEASEL.
17:58:58 15 And a WEASEL is individual oligonucleotides, each of which
17:59:05 16 themselves are a hundred percent complementary, but are then
17:59:08 17 tethered together.

17:59:09 18 It's sort of this separate idea of having two
17:59:12 19 things tethered together by a linker, or three things
17:59:15 20 tethered together by a linker. But it's abundantly clear
17:59:19 21 from the specification that these claims are not intended to
17:59:22 22 cover WEASELS. These claims are limited to things that are
17:59:25 23 20 to 31 nucleotides in length. And the examples in the
17:59:28 24 specification are much longer than that.

17:59:30 25 For example, the only exon 53 WEASEL that's set

17:59:34 1 forth -- and this is at Table 1C, Column 21, is 75
17:59:39 2 nucleotides long or 75 bases long, not 20 to 31. And it's
17:59:44 3 of course perfectly appropriate, claims don't have to cover
17:59:47 4 every single embodiment in the specification. They
17:59:51 5 shouldn't be contorted to do so.

17:59:54 6 Now, just one more point, I think. So in terms
18:00:00 7 of Dr. Dowdy's position on antisense, when they say that the
18:00:15 8 additional bases in the claims antisense oligonucleotide can
18:00:22 9 be random, as Dr. Dowdy explains, that's just fundamentally
18:00:25 10 inconsistent with the plain and ordinary meaning of what an
18:00:28 11 antisense oligonucleotide is.

18:00:32 12 Clarifying that a bay sequence would require a
18:00:35 13 hundred percent complementary throughout the antisense
18:00:41 14 oligonucleotide is consistent, it tightens up Dr. Dowdy's
18:00:44 15 position, the plain and ordinary meaning of an antisense
18:00:48 16 oligonucleotide is something that is highly complementary,
18:00:52 17 if not a hundred percent complementary.

18:00:55 18 The bay sequence construction would further
18:00:57 19 clarify the scope of the claim in a way that's consistent
18:00:59 20 with the plain and ordinary meaning.

18:01:05 21 THE COURT: Don't have any questions. Thanks
18:01:07 22 very much.

18:01:20 23 MS. WILLIAMSON: Your Honor, in preparation, I
18:01:23 24 have prepared some demonstratives for the argument and I
18:01:26 25 actually -- I prepared two different presentations because I

18:01:30 1 wasn't sure of the scope that -- of argument that you wanted
18:01:35 2 and what kind of clarification that you might be seeking.

18:01:39 3 So at the outset, I'd just like to say that if
18:01:45 4 you were to adopt or pursue my colleague's argument that bay
18:01:52 5 sequence should be now reconstrued as 100% complementary,
18:01:56 6 you would be full stop reversing Judge Williams' opinion.
18:01:59 7 It would not be a clarification. It would be a full
18:02:02 8 reversal of his opinion. It is also entirely inconsistent
18:02:07 9 with the arguments that are in the motion in limine.

18:02:10 10 THE COURT: Well, it would be -- it would be
18:02:24 11 clarifying his construction but it certainly would be
18:02:27 12 different than the opinion text right before he announced
18:02:31 13 what his construction was. I can't disagree with that.

18:02:34 14 MS. WILLIAMSON: Yes. So if we could just turn
18:02:37 15 to the MIL presentation.

18:02:43 16 MR. SIKORA: I'm sorry, Your Honor, is there a
18:02:44 17 button that needs to be pressed on your end to permit
18:02:47 18 viewing on the lectern or something?

18:02:48 19 THE COURT: We're working on it.

18:03:00 20 MS. WILLIAMSON: So if we could proceed to
18:03:03 21 slide --

18:03:04 22 THE COURT: I mean, he says -- before you get to
18:03:06 23 that, he says any sequence of bases that is part of the
18:03:10 24 antisense oligonucleotide. And your view is that that means
18:03:22 25 that read in the context of the claim, not the whole

18:03:27 1 antisense oligonucleotide has to be a hundred percent
18:03:31 2 complementary.

18:03:31 3 But his construction doesn't really resolve that
18:03:34 4 issue, but I get that what he said seems to be contrary to
18:03:39 5 what they said in his opinion. And you-all made arguments
18:03:42 6 about this before the Markman hearing and he -- I don't
18:03:46 7 think I can dispute that he appeared to reject theirs and
18:03:50 8 adopt yours, and that your experts proceeded on that basis.

18:03:54 9 MS. WILLIAMSON: Yeah. So actually, could we --
18:03:57 10 so here is the -- the crux of the dispute was whether a bay
18:04:01 11 sequence can be a portion of the claimed oligonucleotide or
18:04:04 12 whether it must include all bases of the antisense
18:04:10 13 oligonucleotide.

18:04:10 14 And the Court found that there was no evidence
18:04:13 15 in the claims, specification or prosecution history, to
18:04:16 16 support limiting a bay sequence to the entirety of the
18:04:19 17 claimed antisense oligonucleotide. That was based in part
18:04:24 18 on several points, if we proceed forward. This is the
18:04:29 19 claim's language here. An antisense oligonucleotide of 20
18:04:36 20 to 31 bases comprises a bay sequence. That is 100%
18:04:42 21 complementary. And two of the key parts of the claim
18:04:45 22 language to Judge Williams' opinion are the comprising
18:04:48 23 terms, obviously, and the term "a" base sequence with the
18:04:53 24 article "a".

18:04:55 25 And he found that indeed the patentee chose to

18:04:59 1 recite "a" base sequence as a separate claim term from
18:05:05 2 antisense oligonucleotide. If Your Honor were to find the
18:05:07 3 entire sequence 100% complementary, you would be conflating
18:05:11 4 the term antisense oligonucleotide with the base sequence.
18:05:15 5 So it would no longer be an antisense oligonucleotide
18:05:20 6 comprising a base sequence among other things, it would be
18:05:24 7 just that one thing.

18:05:27 8 And so that is a construction that is highly
18:05:32 9 disfavored in the Federal Circuit. The claim -- sorry.
18:05:37 10 This is what we see when we adopt Sarepta's language, that
18:05:43 11 20 to 31 bases comprising a base sequence that is 100%
18:05:47 12 complementary, that portion of the claim is literally
18:05:50 13 omitted. It's just deleted.

18:05:53 14 And it becomes an antisense oligonucleotide of
18:05:57 15 20 to 31 bases that is 100% complementary. If that's what
18:06:02 16 Sarepta had wanted, that's what Sarepta should have claimed
18:06:05 17 in the first place. But they elected a comprising claim,
18:06:08 18 which is different than the NS claims that are at issue in
18:06:13 19 this suit.

18:06:14 20 We elected a consisting of claim. They elected
18:06:17 21 a comprising of claim and then they had named elements after
18:06:21 22 that included a base sequence.

18:06:28 23 So as the Court found, the plain language of the
18:06:32 24 claim suggests the claimed antisense oligonucleotide
18:06:35 25 includes a base sequence that meets subsequently recited

18:06:38 1 limitations. The claim language does not require the
18:06:42 2 claimed antisense oligonucleotide, consists only of the
18:06:46 3 recited base sequence.

18:06:54 4 So then we look to the next -- so in addition to
18:06:57 5 reading out comprising, Sarepta's construction also reads
18:07:03 6 out "a" or "an", which is an open meaning term, and suggests
18:07:07 7 additional portions. So "a" base sequence plus another base
18:07:14 8 sequence.

18:07:15 9 So there is no language in the claims or the
18:07:18 10 specification that necessitates a departure from the general
18:07:21 11 rule, which is what the Court found, that as a matter of
18:07:24 12 law, one would read a base sequence as a part of the
18:07:28 13 antisense oligonucleotide.

18:07:31 14 In addition, when we go through the other
18:07:35 15 factors, we also see -- and this is part of a list of
18:07:37 16 problems with Sarepta's proposed construction. It reads out
18:07:41 17 comprising, it would conflate two claim terms so it doesn't
18:07:47 18 give them their full meaning, and the construction renders
18:07:51 19 that term superfluous.

18:07:53 20 So my colleague said their construction
18:07:57 21 preserves meaning with respect to the 100% complementarity
18:08:01 22 because the 12 consecutive bases supplies that
18:08:07 23 functionality. That's just not correct. The claim term
18:08:11 24 requires 100% complementarity, and that can go beyond the 12
18:08:15 25 consecutive bases, it's not just those bases. It says at

18:08:20 1 least those 12 bases but is also 100% complementary. So
18:08:23 2 more than the 12 bases of seek ID can be 100% complementary,
18:08:27 3 so that term is not superfluous under our reading.

18:08:31 4 Further, the particular embodiments that are
18:08:35 5 recited in the specification, preferred embodiments do not
18:08:39 6 fit into that claim language. The specification
18:08:43 7 specifically contemplated antisense oligonucleotides that
18:08:49 8 are not 100% complementary. It says that flat out, that the
18:08:53 9 antisense oligonucleotides of the claim that are in the
18:08:58 10 specification need not be 100% complementary.

18:09:01 11 My colleagues also mentioned WEASEL. It
18:09:04 12 includes WEASEL embodiments that would not be within their
18:09:09 13 reading. So we have at least six canons of claim
18:09:14 14 construction that Judge Williams relied on that are violated
18:09:17 15 by a construction that conflates the antisense
18:09:20 16 oligonucleotides with a 100% complementary base sequence
18:09:26 17 that spans the entirety of the antisense oligonucleotides.

18:09:30 18 And this is the portion of the specification
18:09:32 19 that I was referring to. It says, "An antisense molecule
18:09:37 20 need not be 100% complementary."

18:09:40 21 This is also consistent with Dr. Dowdy, --
18:09:44 22 Dr. Dowdy's subsequent opinions where he says that he
18:09:46 23 recognizes that antisense and base sequence are separate.
18:09:53 24 So he's going to construe antisense on top of base sequence
18:09:58 25 and say that the term "antisense" carries with it a

18:10:02 1 complementarity requirement.

18:10:04 2 And he acknowledges that even under his POSA's
18:10:08 3 definition, that the antisense oligonucleotide can tolerate
18:10:13 4 one or two mismatches. So that would be inconsistent with
18:10:16 5 the finding that the claims require 100% complementary.

18:10:19 6 THE COURT: You agree that antisense
18:10:21 7 oligonucleotides is a limitation, though, right? The
18:10:23 8 preamble is limiting.

18:10:26 9 MS. WILLIAMSON: It was our position that it was
18:10:28 10 not, but if Your Honor -- if Your Honor is inclined to
18:10:32 11 determine that it is, we can live with that. And we think
18:10:35 12 it can be separately construed and it can preserve the
18:10:38 13 meaning that both of the parties have based their expert
18:10:42 14 reports upon.

18:10:43 15 You know, at this stage, to be clear, I don't
18:10:47 16 think that either party has properly opined on a scope of
18:10:52 17 the claims that's limited to only 100% complementary
18:10:56 18 antisense oligonucleotides. We would be highly prejudiced
18:11:00 19 by going to trial on the current set of opinions because
18:11:02 20 they just don't address that construction. They address a
18:11:06 21 construction where the base sequence is 100% complementary.

18:11:11 22 And Dr. Dowdy has given further opinions that it
18:11:14 23 should be limited to up to what we think is four mismatches,
18:11:18 24 based on his deposition testimony.

18:11:21 25 Dr. Hastings has responded that in her practice,

18:11:24 1 she has sought patents on antisense oligonucleotides that
18:11:28 2 are up to 70 percent complementary, so 30 percent
18:11:33 3 noncomplementary.

18:11:33 4 So there's a dispute in the record amongst the
18:11:36 5 experts on okay, yes, we agree that not all antisense
18:11:40 6 oligonucleotides are 100% complementary. That's well known
18:11:44 7 and agreed to. But in the record, there's a factual dispute
18:11:49 8 about the level of complementarity that is necessary.

18:11:52 9 And I think if Your Honor is going to issue a
18:11:55 10 clarification, it should be to that term, "antisense
18:12:01 11 oligonucleotides," not a disruption of Judge Williams'
18:12:05 12 construction about the base sequence, which for the reasons
18:12:08 13 I've said is legally correct.

18:12:09 14 THE COURT: Well, what's the jury even going to
18:12:11 15 take from it, I guess is what I'm wondering? So again, I
18:12:15 16 don't want to beat a dead horse here, but he says -- the
18:12:21 17 Court says, "A base sequence means any sequence of bases
18:12:25 18 that's part of the antisense oligonucleotides."

18:12:28 19 How does a jury understand that that means it
18:12:31 20 can include -- right. It can have a part that is 100%
18:12:36 21 complementary to consecutive bases in the target region and
18:12:40 22 a part that can't. I mean, it's your expert that is going
18:12:42 23 to say that, but his construction doesn't say that.

18:12:48 24 MS. WILLIAMSON: I'm sorry, Your Honor, could
18:12:49 25 you repeat --

18:12:50 1 THE COURT: Yeah, I'm just sort of saying we
18:12:52 2 all, for those of us who have some experience in this
18:12:56 3 technology, we all understand what the dispute here is, but
18:12:58 4 the jury is not going to understand that based on this claim
18:13:02 5 construction is all I'm saying.

18:13:03 6 MS. WILLIAMSON: So I think what we'd say is
18:13:05 7 it's a portion. What Judge Williams says is it's -- the
18:13:09 8 base sequence has certain requirements. And here there's
18:13:12 9 really -- there's no actual dispute on infringement, so we
18:13:14 10 don't have to confuse the jury with any kind of
18:13:17 11 infringement.

18:13:17 12 THE COURT: Thank goodness for that.

18:13:19 13 MS. WILLIAMSON: Really, the only thing that we
18:13:21 14 are discussing with the jury that relies on -- that relies
18:13:27 15 on the term "antisense oligonucleotides" now is how large is
18:13:31 16 the genus, what kind of genus are we talking about?

18:13:34 17 THE COURT: Right. And so your expert says it
18:13:36 18 has at least two billion compounds because it can include
18:13:41 19 these random sequences on the end. And then their expert
18:13:44 20 says no, it's really only 2,000 compounds. And then your
18:13:48 21 expert says, you know what, even if it's only 2,000, it
18:13:53 22 still fails for lack of written description and lack of
18:13:56 23 enablement.

18:13:56 24 So you have an opinion on if it's only 2,000,
18:13:59 25 right?

18:13:59 1 MS. WILLIAMSON: Correct. The amount is not
18:14:02 2 2,000, but we have an opinion under Dr. Dowdy's
18:14:05 3 construction. And we're willing to go forward on that and
18:14:09 4 clarify the construction in a way that will frame that issue
18:14:12 5 for the jury in terms of -- in terms of putting bounds on
18:14:18 6 the genus.

18:14:19 7 THE COURT: So I guess my question is, if I
18:14:22 8 don't let NS argue to the jury that this construction that
18:14:29 9 Judge Williams gave you -- or maybe I even clarify it, that
18:14:32 10 says what this doesn't mean is that you can have a part
18:14:35 11 that's complementary and then a whole part that's not at
18:14:38 12 all. If I don't let you say that, you still have a position
18:14:41 13 under 112 and you can move forward with the trial next week?

18:14:44 14 MS. WILLIAMSON: So, as the experts have opined
18:14:47 15 on it so far, Dr. Dowdy's position is that, you know, he
18:14:54 16 construed base sequence and he said, okay, fine, that's 100%
18:14:58 17 complementary. But look here at antisense oligonucleotides,
18:15:02 18 that has to be 100% complementary or highly complementary.

18:15:06 19 If that is the construction that Your Honor
18:15:10 20 adopts or the clarification that you adopt, then the experts
18:15:13 21 have opined on it and our expert has an opinion. And
18:15:16 22 there's a factual dispute about what that highly
18:15:20 23 complementary area would mean.

18:15:22 24 THE COURT: Right.

18:15:22 25 MS. WILLIAMSON: Excluding that highly

18:15:24 1 complementary area from the construction is contrary to the
18:15:26 2 specification, because the specification indication
18:15:29 3 expressly allows for not 100% complementary.

18:15:33 4 All of the experts agree that there are many
18:15:35 5 reasons for mismatches and other things in the design of
18:15:38 6 antisense oligonucleotides.

18:15:40 7 And so just as a matter of science, requiring a
18:15:44 8 hundred percent complementary is not the -- and in NS's
18:15:48 9 respectful view is not the correct response to the ambiguity
18:15:51 10 that might be in the base sequence of the claim.

18:15:58 11 So we would propose that we construe antisense
18:16:00 12 oligonucleotides. We have proposed -- we are proposing now.

18:16:06 13 THE COURT: And then are you going to put on --
18:16:08 14 if we do it that way, Dr. Hastings is not going to say
18:16:12 15 there's two billion species in the genus, right?

18:16:16 16 MS. WILLIAMSON: Correct.

18:16:17 17 THE COURT: And there's not going to be any
18:16:18 18 discussion about "and so, therefore, the Court's base
18:16:22 19 sequence can allow all this other different stuff too"?

18:16:26 20 I'm just trying to figure out how we can fix
18:16:29 21 this without digging a bigger hole or restarting all the
18:16:32 22 expert reports. I understand perfectly what happened here.

18:16:35 23 Is there a path forward?

18:16:36 24 MS. WILLIAMSON: Yes. I think there is. So the
18:16:38 25 construction we would now propose is an antisense

18:16:43 1 oligonucleotide that binds to a pre-mRNA target with
18:16:50 2 sufficient complementarity to avoid nonspecific binding.

18:16:54 3 This is the wording from the specification.
18:16:56 4 Dr. Dowdy relies on this wording in formulating his opinion
18:17:01 5 that an antisense molecule is highly, if not 100%
18:17:06 6 complementary. We think it would be proper or more proper
18:17:09 7 to go to the words of the specification and construe
18:17:12 8 complementarity in this manner.

18:17:14 9 And so there has to be sufficient -- so it would
18:17:17 10 take care of Your Honor's concern that there's this enormous
18:17:21 11 amount of random -- I'm not sure if you said random stuff
18:17:25 12 but --

18:17:25 13 THE COURT: Right. We all understand. Yeah.
18:17:27 14 But I guess it wouldn't take care of their concern that
18:17:29 15 really it needs to be 100%, and they want me to tell the
18:17:33 16 jury that it's 100%.

18:17:35 17 MS. WILLIAMS: But that's not what they said in
18:17:38 18 their MIL. They said they wanted 100% or nearly 100%. They
18:17:43 19 never argued. That was today that they've argued -- they're
18:17:46 20 rearguing claim construction that was done --

18:17:49 21 THE COURT: At my request. At my request
18:17:52 22 because I'm scared that I'm seeing these MILs flying back
18:17:55 23 and forth. And I can resolve them in a way that I think
18:17:57 24 would fix things but might just be digging a deeper hole and
18:18:01 25 then we're going to waste our time next week. And that's

18:18:04 1 what I'm worried about.

18:18:05 2 And so I understand your point. Your expert was
18:18:08 3 in bounds in terms of how they understood what Judge
18:18:11 4 Williams did. If I tell the jury that this requires 100%
18:18:17 5 complementarity because of the language of the claim, and I
18:18:19 6 understand that you disagree with that, do you have a 112
18:18:23 7 defense? What does that do to your expert's ability to
18:18:26 8 opine on 112?

18:18:28 9 MS. WILLIAMSON: We have a 112 defense, but we
18:18:30 10 would need to go back to the board and reformulate it.
18:18:34 11 Because the things we focused on in our expert reports were
18:18:37 12 not what we would focus on if we had been talking about 100%
18:18:40 13 complementary. It's just an entirely different inquiry for
18:18:44 14 us to understand the scope of the claim. The genus would
18:18:48 15 still be quite large.

18:18:49 16 THE COURT: Right. Still 2000, somewhere close
18:18:52 17 to.

18:18:52 18 MS. WILLIAMSON: It's actually quite a bit
18:18:58 19 larger, because we -- and --

18:19:01 20 THE COURT: At least 2000.

18:19:04 21 MS. WILLIAMSON: It's at least 2000 but there
18:19:06 22 are many issues we did not address in our expert reports,
18:19:09 23 changes in different backbone chemistry and other chemical
18:19:14 24 modifications and other things, just because it was not as
18:19:18 25 important.

18:19:18 1 THE COURT: Because you had the 1 in 2 million.
18:19:22 2 And I totally understand that.

18:19:22 3 MS. WILLIAMSON: It was qualitatively unfair for
4 to -- to be forced to go forward without redeveloping, and
18:19:26 5 redoing expert reports on the scope of the genus under a new
18:19:28 6 claim construction and it really would be an entirely new
18:19:31 7 and different claim construction in a reversal of what Judge
18:19:35 8 Williams would do.

18:19:36 9 So I would urge the Court to find a middle
18:19:39 10 ground or even to adopt what Dr. Dowdy is now arguing, that
18:19:44 11 we can resolve this by looking at what is an antisense
18:19:47 12 molecule and what does a POSA believe that that requires.

18:19:52 13 So he says, "1 to 4 mismatches."

18:19:54 14 Our expert says somewhere in the area of 1 to 6
18:19:58 15 mismatches -- if we can go to that.

18:20:07 16 This is from one of the patents, the Bestwik
18:20:10 17 patents that Sarepta's expert relies on in his report. In
18:20:15 18 the specification, it talks about preferably 645,321
18:20:21 19 mismatches. So this is a very, very common scientifically
18:20:25 20 acceptable point of view for what an antisense
18:20:30 21 oligonucleotide is.

18:20:32 22 THE COURT: And understood. Again, maybe if we
18:20:35 23 change the base sequence construction. So I think I hear
18:20:43 24 what you're saying, which is, if the Court clarifies Judge
18:20:53 25 Williams' claim construction and essentially reverses his

18:20:55 1 his reasoning behind it, that you would not be prepared to
18:20:59 2 go forward next week?

18:21:00 3 MS. WILLIAMSON: That's correct.

18:21:01 4 THE COURT: All right. Let me hear from the
18:21:04 5 other side. Just on the issue --

18:21:08 6 MS. WILLIAMSON: Sorry, I just wanted to --

18:21:10 7 THE COURT: You want to finish your --

18:21:12 8 MS. WILLIAMSON: Oh, no. That's okay. I just
18:21:13 9 wanted to make sure to mention that its still our position
18:21:16 10 that the base sequence would be in the preamble.

18:21:19 11 MR. SIKORA: So, in other words, Your Honor --

18:21:21 12 THE COURT: That the preamble would be limiting?
18:21:24 13 No.

18:21:24 14 MR. SIKORA: So there are actually three
18:21:26 15 different interpretations that are floating around. One is
18:21:29 16 what Jude Williams adopted, which is only the base sequence
18:21:32 17 has a complementary limitation and the preamble is
18:21:36 18 nonlimiting.

18:21:37 19 The one that counsel argued today is that the
18:21:39 20 entire antisense oligonucleotide is exactly 100% and the one
18:21:44 21 that we were proposing, that they argued in the motion in
18:21:48 22 limine, that Dr. Dowdy is arguing for, is that the entire
18:21:51 23 thing is mostly that the base sequence is 100. That's the
18:21:55 24 one that we were proposing.

18:21:56 25 THE COURT: Right. Fully understand. Yep.

18:22:09 1 MR. RAICH: So, I think first of all, that the
18:22:13 2 claim should be construed ultimately just based on what is
18:22:17 3 the proper construction of the term. It's not ultimately a
18:22:21 4 question of what's convenient, it's what is the appropriate
18:22:25 5 construction? And so we do think that base sequence needs
18:22:30 6 to be looked at very carefully and very closely. I think
18:22:33 7 that's the first thing.

18:22:36 8 Dr. Dowdy, in talking about the meaning of
18:22:40 9 antisense was operating under the Court's construction. And
18:22:43 10 so when Dr. Dowdy said that there could be a mismatch in the
18:22:48 11 context of an oligonucleotide, that was operating under the
18:22:53 12 construction that we were operating under, but he also
18:22:57 13 performed calculations in terms of the scope of the genus,
18:23:02 14 in the context of the report where there was 100%
18:23:09 15 complementary, which is essentially what we are adopting as
18:23:11 16 the base sequence.

18:23:12 17 THE COURT: So you're ready to go forward next
18:23:14 18 week, but they're not.

18:23:17 19 MR. RAICH: Well, respectfully, I think that
18:23:18 20 they are, because first of all, they responded at least to
18:23:21 21 doctor -- as I said before, they have other sort of theories
18:23:24 22 of the case that aren't just based on the scope of the
18:23:32 23 genus. And as sort of an additional point, you know, I
18:23:39 24 heard Ms. Williamson state that they would agree with --
18:23:45 25 there's a new construction that they -- it's the first time

18:23:47 1 that we've heard about it, that wasn't set forth in any of
18:23:51 2 their expert reports.

18:23:51 3 THE COURT: I'm sure they were thinking about it
18:23:53 4 all weekend because I -- to be this late -- and on Friday.

5 MR. RAICH: Understood. Understood.

18:23:56 6 THE COURT: So I'm not blaming them for that.

18:23:58 7 MR. RAICH: They said that Dr. Dowdy, you know,
18:24:01 8 agreed with having four mismatches in an oligonucleotide. I
18:24:08 9 also don't think that's correct. And I heard in argument,
18:24:10 10 going back to the base sequence, about how we're reading out
18:24:14 11 comprising from the claim because it's a comprising claim.

18:24:18 12 And antisense oligonucleotide has different
18:24:22 13 parts to it. It has a base sequence, it has a chemical
18:24:26 14 backbone that supports the bases and holds them in place.
18:24:30 15 It may have a modification at the end, like a tail it's
18:24:35 16 called. And so we're not reading out comprising. It's an
18:24:40 17 antisense oligonucleotide with the base sequence, whatever
18:24:43 18 those bases are, is 100% complementary over the full length.

18:24:47 19 And then there are additional parts other than
18:24:50 20 the base sequence such as the particular chemical backbone.
18:24:54 21 That's why comprising is appropriate there.

18:24:59 22 THE COURT: So -- and I get the point on claim
18:25:01 23 construction. I'm trying to think of the most efficient way
18:25:05 24 to go forward. This Court's construction of "base sequence"
18:25:13 25 doesn't tell the jury really one way or the other anything

18:25:16 1 about the dispute we're talking about here, does it?

18:25:19 2 MR. RAICH: You're right. It's sort of
18:25:23 3 interpreting it in the broader context of the claim and what
18:25:26 4 the effect of it is. So I think it's almost like you have
18:25:28 5 to explain what the dispute is to even understand the effect
18:25:32 6 of the construction. So I do agree with that.

18:25:35 7 THE COURT: And so the plaintiff has proposed
18:25:38 8 that we go -- we let the jury hear the case and I'm going to
18:25:44 9 give the construction, which they haven't asked for a
18:25:48 10 clarification of. They can tell the jury, what this means
18:25:50 11 is, you can hook on -- a bunch of junk onto the end and that
18:25:54 12 that still falls within the Court's claim construction.

18:25:56 13 You want to be able to say, it doesn't or you're
18:26:00 14 happy with letting that go forward and then you-all can talk
18:26:04 15 to the jury about what antisense oligonucleotide means and
18:26:08 16 it means it can have up to four mismatches.

18:26:11 17 You want to be able to go forward or you want me
18:26:14 18 to tell the jury that this has to be 100% complementary?

18:26:18 19 MR. RAICH: I think from our perspective, saying
18:26:22 20 something other than 100% complementary would ultimately be
18:26:29 21 improper, but I also think the case is primed to go forward
18:26:33 22 because Dr. Hastings has offered additional opinions that
18:26:38 23 relate to things other than just the scope of the genus.

18:26:44 24 As I mentioned before, there is arguments that
18:26:46 25 she makes about things in the specification. So I think

18:26:53 1 that the case is primed to go forward and that it should do
18:26:56 2 so with the appropriate construction.

18:26:59 3 MR. MORIN: May I add something, Your Honor? I
18:27:01 4 don't mean to play two-on-one kind of thing but may I add
18:27:04 5 something just --

6 THE COURT: Sure.

18:27:05 7 MR. MORIN: -- just from the perspective of
18:27:06 8 sitting in that chair.

18:27:08 9 I want to reemphasize something that Mr. Raich
18:27:11 10 said, which is, we think that the clear construction of the
18:27:19 11 term requires 100% complementary bases. And we think that
18:27:24 12 ultimately, respectfully, to Judge Williams, that the folks
18:27:31 13 in Washington, we think are going to see it that way. I
18:27:34 14 think Your Honor should respectfully construe the claim the
18:27:37 15 way the claim is correct.

18:27:38 16 And if our friends need more time, I understand
18:27:41 17 that putting off a trial is drastic remedy, but if they
18:27:46 18 think they need more time in view of that construction, that
18:27:49 19 is the more efficient way to deal with things and we get it
18:27:53 20 right and we come back and we do it. It's never the first
18:27:57 21 choice of anybody obviously.

18:27:59 22 But, it is a -- the most important thing is
18:28:03 23 to -- and we think Your Honor has identified -- potentially
18:28:06 24 an issue that we felt very strongly about the first time
18:28:09 25 around, when they say anything about what Dr. Dowdy did,

18:28:12 1 it's obviously operating under what Judge Williams said was
18:28:15 2 the construction of the claim. He had to do with it what he
18:28:17 3 could, which he did. But anything saying it could be nearly
18:28:21 4 100% was in the context of the ruling on base sequence
18:28:25 5 already that he was required to operate under. And we told
18:28:27 6 them that that's a fixed body.

18:28:29 7 But if it would mean that, it would mean that,
18:28:32 8 but the important thing is to get it right now, Your Honor.

18:28:35 9 THE COURT: All right. Appreciate it. I hope
18:28:37 10 everyone understands, I didn't mean to cutoff anyone's
18:28:40 11 *Markman* arguments. I can assure you, I'm fully aware of
18:28:44 12 everyone's positions. We've poured over the *Markman*
18:28:48 13 briefing. We've reviewed the patents. We've reviewed Judge
18:28:53 14 Williams' claim construction order. I'm worried about
18:28:59 15 digging a deeper hole than what I think we might already be
18:29:02 16 in, but I'm not prepared to make a final decision on what
18:29:08 17 should be done.

18:29:09 18 I am hearing from plaintiff, though, that if the
18:29:12 19 Court is inclined to tell the jury that base sequence
18:29:21 20 requires 100% complementary, that plaintiff needs more time.

18:29:29 21 It looked to me from the expert reports like
18:29:33 22 there was a 112 defense still in there, but I can't -- let
18:29:43 23 me put it this way: I can't understand plaintiffs' point
18:29:46 24 that they would have emphasized different things in the
18:29:49 25 expert report. And I appreciate that.

18:29:54 1 So I guess we should have addressed this right
18:29:58 2 at the outset. So why don't we all sleep on it and I'll
18:30:04 3 sleep on it. I am in the middle of another trial right now.
18:30:10 4 We'll work as hard as we can at night and during breaks to
18:30:14 5 see if we can come up with an answer.

18:30:16 6 I have to tell you, as you might have guessed,
18:30:18 7 my inclination is that there does need to be a clarification
18:30:23 8 or a change to Judge Williams' base sequence claim
18:30:26 9 construction. And what my experience has told me, is that
18:30:37 10 going to the jury trial and hoping things work out, doesn't
18:30:40 11 actually work the way you think it's going to work and that
18:30:44 12 wasting people's time, if you're going to ultimately change
18:30:47 13 something later, is not a preferred course of action.

18:30:52 14 So those are my thoughts on that. And I realize
18:30:57 15 that the outcome of that has to do with how we're going to
18:31:02 16 rule on No. 3, as well as whether we're going to have the
18:31:06 17 trial at all.

18:31:07 18 So we do need to give the court reporter a break
18:31:10 19 because she has now been going for nine hours, transcribing.
18:31:14 20 So let's proceed this way. We're going to work on what we
18:31:18 21 think about the claim construction. It doesn't sound like
18:31:23 22 we have agreements between the parties about how we could
18:31:27 23 potentially proceed with the expert reports we have, but I'd
18:31:29 24 like you to continue to talk. And if somebody thinks of an
18:31:32 25 idea of how we might go forward, I'm happy to hear it

18:31:36 1 because we have you on the calendar and we moved a lot
18:31:39 2 around to get everybody to trial next week, despite being
18:31:42 3 only assigned this case a few weeks ago.

18:31:49 4 Why don't we plan to have a letter from the
18:31:55 5 parties by Wednesday evening. Just telling us if there's
18:32:11 6 been any change to their position, again, the position that
18:32:13 7 I'm hearing from plaintiffs is that, if there's a change to
18:32:17 8 the claim construction, that we need to redo the expert
18:32:20 9 reports.

18:32:21 10 And defendants' position, that we could move
18:32:24 11 forward based on what we have so far. And then we'll have a
18:32:28 12 status call Thursday at 10 a.m. and we'll put the number on
18:32:37 13 the court's line. And then if we're going to move forward,
18:32:42 14 we'll discuss the rest of the issues in the pretrial order,
18:32:49 15 none of which were all that challenging and we're ready to
18:32:54 16 tell you what our rulings are on those.

18:32:57 17 I hate to leave it up in the air like this for a
18:33:02 18 couple of days but this is where we're at. Does anybody
18:33:05 19 have a better idea?

18:33:06 20 MR. MORIN: I don't. I wanted to address just a
18:33:08 21 couple things, Your Honor, hopefully in the sake of
18:33:11 22 efficiency. I know it's late.

18:33:12 23 The first is, there was a dispute between the
18:33:15 24 parties about the number of hours for the bench trial on
18:33:18 25 unenforceability. And we figured we would tell you what we

18:33:21 1 told our friends just before this hearing.

18:33:24 2 We've decided not to pursue our unenforceability
18:33:27 3 claim against them. We looked at it and decided it was
18:33:31 4 redundant with the obviousness claim and it will arise or
18:33:34 5 fall -- we think rise -- with our obviousness arguments, but
18:33:37 6 since they were somewhat redundant in what the result was
18:33:41 7 going to be, that we would take that off the table, which I
18:33:44 8 think means the competing proposals, them for four hours per
18:33:48 9 side and us for two would be cut in half. So half of that
18:33:52 10 will happen then. So hopefully that's welcome news for the
18:33:56 11 Court on that front.

18:33:57 12 I should also advise the Court that we have not
18:34:00 13 yet resolved the breach of contract issue. We're optimistic
18:34:05 14 we will. Compared to the patent issues, it's very low -- I
18:34:07 15 won't say the amount, but a very low -- very, very low
18:34:11 16 amount compared to the other main issues in the case. We
18:34:14 17 have a proposal out to them.

18:34:15 18 Reasonably, their folks are on Golden Week, so
18:34:20 19 they haven't been able to respond. We're hoping to take it
18:34:23 20 off your table but our friends propose -- and we are not
18:34:26 21 contesting that -- if that still remains, which we're very
18:34:29 22 optimistic it won't, again, it's a small amount, that with
18:34:34 23 Your Honor's blessing, we would do it while the jury is
18:34:37 24 deliberating a week from Friday and no more than one hour
18:34:40 25 per side.

18:34:41 1 We think it may be 15 or 20 minutes, it's very
18:34:43 2 little, we think, on that. But we agree with our friends
18:34:46 3 that if it's not resolved with the Court's blessing, we
18:34:50 4 would do it that Friday.

18:34:51 5 One other thing that I'm hesitant, I know you
18:34:54 6 want to get out of here, but we have -- our friends brought
18:34:59 7 up an issue percolated by an e-mail from them last Tuesday,
18:35:03 8 that has to deal with some standing and damages issues, that
18:35:07 9 they would like -- we think we're still fine but they would
18:35:10 10 like some expedited briefing on this week.

18:35:14 11 And they proposed -- and I think they were going
18:35:16 12 to propose that they would file a brief tomorrow and we
18:35:19 13 would file a response on Wednesday. I only say that because
18:35:21 14 if the Court were inclined to postpone the trial and pick
18:35:25 15 another day, this expedited briefing on damages and standing
18:35:29 16 and stuff could be dealt with in a more deliberate and
18:35:34 17 considered fashion.

18:35:37 18 It has to do with an issue they raised last
18:35:40 19 Tuesday. We identified some additional agreements in
18:35:43 20 response to that that hadn't been produced that we did
18:35:48 21 produce and investigation and discussions have been going on
18:35:50 22 kind of nonstop to kind of bring it to Your Honor in a
18:35:54 23 reasonable way.

18:35:55 24 But later in your cross, the issue of the claim
18:35:58 25 construction, it might be a prudent decision for us to be

18:36:03 1 able to take sometime for the briefing and the discovery of
18:36:07 2 the information for Your Honor rather than have layering on
18:36:10 3 top of your other bench trial and these claim construction
18:36:14 4 issues in these other briefs, sets of briefs on this new
18:36:17 5 issue where they are now contending, as far as I can tell
18:36:20 6 that there's a standing and a damages issue and we are going
18:36:23 7 to be opposing that.

18:36:24 8 A little bit of daylight before people are all
18:36:28 9 in town from the other people and a little daylight to come
18:36:32 10 and try this case once both the claim construction issue is
18:36:36 11 resolved and that's resolved, might be a more prudent way to
18:36:40 12 do things. I say that not lightly. Trial dates being moved
18:36:43 13 are -- I know Your Honor had to move things around, like you
18:36:46 14 said, and everybody does and the clients and the witnesses
18:36:49 15 and I appreciate that but we want to get it right, Your
18:36:52 16 Honor.

18:36:52 17 So I only raise that so it's not a surprise to
18:36:55 18 Your Honor.

18:36:56 19 THE COURT: All right. Thank you very much.

18:36:57 20 MR. SIKORA: Your Honor, just a quick point of
18:37:00 21 clarification, because when somebody says "standing," that
18:37:03 22 usually implicates a bigger deal.

18:37:05 23 Our current understanding is there's at least a
18:37:08 24 13-month period within the damages period in which the
18:37:11 25 Sarepta Therapeutics entity, the plaintiff on their patent

18:37:16 1 claims in the lawsuit, lost exclusive rights.

18:37:17 2 And so that's our current understanding. It's
18:37:20 3 still evolving. The agreements weren't produced during
18:37:24 4 litigation. They involved internal transfer with Sarepta.
18:37:27 5 We're prepared to go forward on briefing what we think the
18:37:30 6 issue is, including the discovery issues and the failure to
18:37:32 7 disclose those timely tomorrow by 5 p.m.

18:37:36 8 Sarepta agreed to their responsive brief, a
18:37:41 9 5-page letter brief by Wednesday of the same and so we're
18:37:45 10 happen to do that if Your Honor is willing to entertain that
18:37:49 11 briefing.

18:37:49 12 THE COURT: Counsel?

18:37:51 13 MR. MORIN: As we indicated to our friends, we'd
18:37:53 14 be willing on that briefing schedule but I guess what I'm
18:37:56 15 saying is --

16 THE COURT: I understand, yeah.

18:37:57 17 MR. MORIN: -- there's a lot of moving parts and
18:37:58 18 if you have to deal with 5 p.m. and 5 p.m. on damages being
18:38:01 19 changed, also in addition to the claim construction and he
18:38:05 20 says he doesn't see a standing issue, but we heard issues of
18:38:10 21 when exclusivity was, which --

18:38:12 22 THE COURT: I understand. So here's what I'll
18:38:14 23 say: I'm not going to decide the damages issue if we're not
18:38:17 24 going forward with the trial next week. I'm not going to
18:38:20 25 decide it on Thursday night. So with that in mind, I'm

18:38:24 1 hearing from plaintiffs that maybe you need to talk to your
18:38:28 2 people and confirm about whether or not you want to go
18:38:31 3 forward if the Court is inclined to change the claim
18:38:34 4 construction or amend the claim construction.

18:38:36 5 And so if you know that you're not going to go
18:38:38 6 forward, you don't have to file your damages brief when
18:38:42 7 you've agreed with them, but you have to tell them you're
18:38:45 8 not planning on going forward. Does that make sense?
18:38:47 9 Otherwise, we're going to proceed with the briefing.

18:38:49 10 MR. SIKORA: And just to clarify, Your Honor.
18:38:52 11 Our view was that if the interpretation from Dr. Dowdy in
18:38:56 12 his report of some number of mismatches but not the full,
18:38:59 13 everything, if the construction advanced by them in their
18:39:05 14 expert reports was the one -- the middle ground that we
18:39:09 15 referred to, if that was adopted by the Court clarifying the
18:39:13 16 preamble term antisense, we would be prepared to go forward
18:39:17 17 next week. It's simply if Your Honor reversed Judge's
18:39:20 18 Williams entirely, that we would more time.

18:39:24 19 And that is what we obviously contend is the
18:39:24 20 correct result and the one that we think the folks in
18:39:29 21 Washington would agree with.

18:39:31 22 THE COURT: Right.

18:39:32 23 MR. MORIN: Thank you, Your Honor.

18:39:34 24 THE COURT: Okay. I guess we'll talk to
18:39:37 25 everybody on Thursday. I didn't take any of this lightly.

18:39:40 1 I hope everyone knows. We'll work as hard as we can to get
18:39:44 2 you an answer.

18:39:45 3 MR. MORIN: We appreciate your Honor's time.

18:39:49 4 COURT CLERK: All rise.

18:39:52 5 (Court adjourned at 6:39 p.m.)

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10 I hereby certify the foregoing is a true and
11 accurate transcript from my stenographic notes in the
12 proceedings.

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/s/ Stacy M. Ingram, RPR
Official Court Reporter
U.S. District Court

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